UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	)	MD 15-02641-PHX-DGC
Lisa Hyde and Mark Hyde, a married couple,	)	Phoenix, Arizona **October 1, 2018**
Plaintiffs,	)	
v.	)	CV 16-00893-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation, and Bard Peripheral Vascular, an Arizona corporation,	)	
Defendants.	)	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 10 - A.M. SESSION

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Proceedings Reported by Stenographic Court Reporter
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P R O C E E D I N G S

(Proceedings resumed at 8:30 a.m.)

(Jury not present.)

THE COURT: Good morning, everybody.

MR. LOPEZ: Good morning, Your Honor.

MR. ROGERS: Morning, Your Honor.

THE COURT: Counsel, I don't have the ruling on the Rule 50 motion yet. There's some more cases I want to read.

I will tell you, so as not to keep you in suspense, that I do not think I'm going to grant it on the liability issue or punitive damages. I do, however, want to read more cases on the loss of consortium claim and on the recoverability of the defibrillator.

There are some more cases on those that I haven't had a chance to read, and I hope to be able to get all of that done and get the decision to you maybe by the end of the day. I've got a noon conference call that may preclude me from doing that as well, but I'll get it to you as soon as I can.

Are there matters you all want to raise this morning?

MR. O'CONNOR: I don't think anything for the plaintiff, Your Honor.

MR. ROGERS: Nothing from defendants, Your Honor.

THE COURT: Tell me what we're covering today.

MR. ROGERS: Well, we will continue, obviously, with Mr. Carr to begin with.

THE COURT: Right.

MR. ROGERS: And he'll be followed by Shari O'Quinn, another fact witness. As far as expert witnesses -- oh, and we'll also have another fact witness, Andre Chanduszko. And experts, we will have Dr. Poll, P-O-L-L, who is an expert cardiologist, and then also, probably toward the latter part of the day, we'll have Donna-Bea Tillman, our regulatory expert.

THE COURT: All right. You can go back to business. I'm going to get plugged in, and then we'll bring the jury in at 9:00 o'clock.

(Recess taken, 8:32 a.m. to 9:00 a.m.)

(Jury present.)

THE COURT: Good morning, ladies and gentlemen.

JURY MEMBERS: Morning.

THE COURT: Hope you had a nice weekend. Thanks for being with us. We're going to pick up where we left off on Friday with the testimony of Mr. Carr.

You may proceed, Mr. Rogers.

MR. ROGERS: Thank you, Your Honor.

ROBERT MICHAEL CARR JR.,

called as a witness herein by the defendants, having been previously duly sworn or affirmed, resumed the stand and continued to testify as follows:

DIRECT EXAMINATION (Continued)

BY MR. ROGERS:

Q. Good morning, Mr. Carr.

A. Good morning.

Q. I hope you had a nice weekend.

A. I like the rain.

Q. Mr. Carr, when we ended on Friday, we had just finished speaking about some animal testing that had been performed on the G2 filter. And I'm going to pick it up from there.

In addition to the animal testing, did Bard also perform what is called bench testing on the G2 filter?

A. Yes, we did.

Q. And can you describe for the jury what bench testing means.

A. So it's a testing that's done in a -- typically in a laboratory setting, where we test different functions of the device, pull testing, tensile testing, different things that we can do in the laboratory, not in an animal, not in a person.

MR. ROGERS: All right. Scott, would you mind pulling up Exhibit 5302, please.

BY MR. ROGERS:

Q. And, Mr. Carr, can you see that document on your screen?

A. Yes.

Q. And can you tell us what it is?

A. It is the protocol for the G1A design verification and validation testing.

MR. ROGERS: Your Honor, I move this document into evidence.

MR. O'CONNOR: Objection. 602, Your Honor.

THE COURT: I think you need to lay additional foundation.

MR. ROGERS: I will be glad to.

BY MR. ROGERS:

Q. Mr. Carr, in your work as an engineer at Bard, were you familiar with this document?

A. Yes.

Q. And were you one of the participants in the preparation of this document?

A. Partially, yes.

MR. ROGERS: Your Honor, I move this into evidence.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit No. 5302 admitted into evidence.)

MR. ROGERS: May we display?

THE COURT: You may.

BY MR. ROGERS:

Q. Now, Mr. Carr, is this the first page of the document that you just described?

A. It appears to be, yes.

Q. And so we see on the left-hand side there that it says G1A. Can you tell us what that is?

A. It's the name for the device that ultimately became the G2 filter.
Q. So while the G2 filter was being -- was going through the initial development and testing phase, was it referred to as the G1A?
A. Yes.
Q. And it was later named G2?
A. Yes.
Q. All right. Mr. Carr, can you tell us, please -- I want to break down these two terms.

The first thing we see is design verification. What is that?
A. So that's the type of testing to verify that the device meets its acceptance criteria. So, for example, something's stronger than 5 pounds, for example; versus validation testing, which is it meets a user's need.
Q. And do you have different types of testing to analyze the more mechanical tests versus the user need test?
A. Yes.
Q. And this protocol addresses both of those types of test; right?
A. Yes, it does.

MR. ROGERS: Okay. So if we would, let's go ahead and pull up Exhibit 5303, please.

BY MR. ROGERS:
Q. And, Mr. Carr, do you see this document on your screen?
A. I do.
Q. And can you tell us what this document is?
A. It is the report for the design verification and validation of the G2 filter.
Q. And were you familiar while you were in -- working as an engineer at Bard at this time with this document?
A. Yes.
Q. And did you help prepare parts of this document?
A. Yes.
MR. ROGERS: Your Honor, I move this document into evidence.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit No. 5303 admitted into evidence.)
MR. ROGERS: All right. May we display, please?
THE COURT: You may.
BY MR. ROGERS:
Q. All right. And again, just for the benefit of the jury, Mr. Carr, would you tell them what this is?
A. Again, it's the G1A Recovery filter design verification and validation report.
Q. And the document we saw just a moment ago was the protocol that established the tests that would be done; is that right?

A. Yes.

MR. ROGERS: Let's take a look, please, if you would, in 5303, and let's go to page 9, please.

MR. O'CONNOR: Excuse me, Your Honor. The previous exhibit, what number was that?

MR. ROGERS: It is 5302.

MR. O'CONNOR: Okay. Thank you.

BY MR. ROGERS:

Q. And, Mr. Carr, I'm going to take you through some of these tests that were performed.

And the first thing we see up at the top is 7.0, Test Results and Summary of Data. Can you describe for the jury, just broadly, what are the types of things that are being reported in this document?

A. So the different tests that we do. This first one is a visual and dimensional test. Then there's some performance-based tests later in the document.

Q. All right. And so this particular one that's on the screen, what is the title of that test?

A. Pre-Sterile Dimensional/Visual Inspection Test Results.

Q. And are these the actual results?

A. So this is -- the table below is the summary of the results, yes.

Q. And did the G2 pass the visual inspection test?

A. Yes, it did.

MR. ROGERS: All right. Let's go on to the next page, please.

And, Scott, if you would, can you go to the bottom and pull out Section 7.2.

BY MR. ROGERS:

Q. All right. So, Mr. Carr, what is the title of this test?

A. Post-Sterile Dimensional/Visual Inspection Test Results.

Q. And so what is this test?

A. So it's a -- measures the arm span and the leg span of the filter, so actually how it's -- how wide it is.

Q. And is this, again, a visual inspection test?

A. It's measured, yes.

Q. And how does it differ from the one that we looked at just a moment ago?

A. This one is post-sterile, so after it had been sterilized.

Q. And did the G2 pass this test?

A. Yes, it did.

MR. ROGERS: All right. Scott, would you mind going to page 12 of the document, please.

And if you would, can you pull out Section 7.3.

BY MR. ROGERS:

Q. What is the title of this test?

A. Bench Top Simulated Use Test Results.

Q. And what does this test examine?

A. It examines different performance requirements that are

then tested on the bench.
Q. And one of the things we see on the left-hand side there, one up from the bottom, says Filter Centering.
Do you see that?
A. Yes, I do.
Q. And what is that test?
A. So it's a test where you deploy the filter into a tube, and then you look at that tube on end so you can see down it, and you mark where the center of the filter is in that tube, so was it deployed centered.
Q. And does that essentially look at whether or not, when the filter is deployed, whether it tilts?
A. Yes.
Q. And did the G2 pass this test?
A. Yes, it did.
MR. ROGERS: All right. Scott, if you would, let's go down the page to 7.4. And can we pull that part out?
BY MR. ROGERS:
Q. What is this test?
A. This is the deployment force test. So it is -- it measures the -- how much force or how much, you know -- how many pounds you need to deploy the filter through -- we make a system where it's to mimic the vessels and the structure of the vessels so that the turns and the diameters that are seen in the body, and so we deploy the filter through that and we measure how much

force that takes.
Q. And how do you measure that force?
A. There's a machine that you hook up the back of the delivery system to, and it automatically advances through the model and it measures the force. It keeps track of it.
Q. And so what are the parameters that you're trying to determine when you're measuring the force?
A. We don't want the force to be too high or too -- too -- to be high to the user, so the perception of the user is that it's easy to deploy.
Q. And did the G2 pass this test?
A. It did.
MR. ROGERS: All right. Scott, can you go on to page 13, please. And would you pull out the section at the top, 7.5.
BY MR. ROGERS:
Q. What is this test, Mr. Carr?
A. This is the filter leg radial strength test. And so it measures the outward force that a leg exerts.
Q. And when you say the outward force, do you mean the leg -- the force that it generates when it's pushing against the walls of the cava?
A. Yes.
Q. And so how do you measure that? How is it done?
A. So this is done in between two plates. And you change the

distance between the two plates and you -- it automatically measures the force or the resistance that that element applies.

Q. And if you were designing a filter that is retrievable, what are some of the considerations that you have to take into account as an engineer in determining what is the appropriate amount of radial force that the legs will exert against the walls of the cava?

A. So you don't want it to be too strong, because that would tend to what we call perforate or go through the vessel wall, potentially. And you -- but you want it to be strong enough where it makes sure that each of the elements appose the wall or touch the wall. So it's a balance there.

Q. And did the G2 pass this test?

A. Yes, it did.

MR. ROGERS: All right. Scott, can you take that down? I want to back us up to Document 5302.

BY MR. ROGERS:

Q. And, Mr. Carr, just to reorient ourselves, is this the protocol for these tests?

A. Yes.

MR. ROGERS: And, Scott, if you would go to page 26, please.

Oh, I'm sorry, Your Honor. May we display?

THE COURT: You may.

BY MR. ROGERS:

Q. And, Mr. Carr, what's --

MR. ROGERS: Well, first, Scott, would you pull out Section 9.7, please.

BY MR. ROGERS:

Q. And so, Mr. Carr, is this the protocol for the radial strength arm and leg testing?

A. Yes.

Q. And so what was the size of the cava that you were testing these radial forces in?

A. It was to simulate a 15-millimeter.

Q. And so why 15 millimeters? What's the significance of that?

A. It's the lower end of the expected diameter range.

Q. And why would you want to test radial force in the lower end of the range of sizes of vena cava filters?

A. Because it would actually be the highest force.

Q. Because the cava is smaller?

A. Yes.

MR. ROGERS: All right. And, Scott, if you would, let's go to page 12 of that same document. And can you orient that? Thank you.

And can you pull out Section 6.2.1.3, the middle one. I'm sorry.

BY MR. ROGERS:
Q. And what do we see here, Mr. Carr?
A. This is the specification for the test.
Q. And can you describe for the jury what specifications were selected for this test?
A. So the user requirement, the third column from the left, is that the filter must not perforate the vessel. Then we have -- that gets translated to an engineering specification. So in this case, the G2 radial strength of the legs must be statistically equivalent or less than the SNF legs in a 15-millimeter diameter.
Q. Go ahead. I'm sorry.
A. And then there's a risk quad, so there's a series of calculations that determine how severe that risk is, how well it can be controlled, and how well it can be observed.

And then the acceptance criteria here is -- it's tested variably, and again, the same specification.
Q. Why were you comparing the G2 to the SNF filter, the Simon Nitinol filter?
A. Because the SNF has a relatively high radial strength and there had been observations of caval penetration historically, and so we didn't want it to be that strong. We wanted it to be less.

MR. ROGERS: All right. Scott, would you take that down. And can you go back to document Exhibit 5303.

May we display, Your Honor?

THE COURT: Yes.

MR. ROGERS: And can you go to page 13, please.

BY MR. ROGERS:

Q. And under 7.5, that's the results of the radial strength testing?

A. Yes, it is.

Q. And I believe you may have said this before, but did the G2 pass these tests?

A. Yes, it did.

MR. ROGERS: All right. So let's -- can you take that down, Scott? And let's pull out the next section, 7.6.

BY MR. ROGERS:

Q. What is this test?

A. So this is the filter removal force, which, as named, is the force required to remove the filter from the vessel. Again, from a user point of view, you don't want the perception to be that it's hard to remove, so you then assign a force to that and it must be under it.

Q. And how do you measure that force?

A. With a gauge hooked up to the removal system in this case, and as you remove it, you monitor the load.

Q. How did you determine what would be the right amount of force to be used to retrieve a filter?

A. We worked with physicians, interventional radiologists who

implant filters, to assess was it too strong or too much force. So it really is a sense or a -- you know, how they felt.

Q. And according to this report, did the G2 pass this test?

A. Yes.

MR. ROGERS: Scott, would you take that down, please? And go to the next page. And can you pull out Section 7.8.

BY MR. ROGERS:

Q. All right. Mr. Carr, we see up at the top where it says Tensile Strength. Do you see that?

A. I do.

Q. And can you describe for the jury what tensile strength is?

A. So this is testing two different joints where we either glue or weld two pieces together; in this case, a dilator to a hub. There's a fitting on the back of a tube that allows you to hook up a syringe to it, for example. That joint or bond, we measure the force required to break it, how strong is that bond.

And then the same -- the spline is a piece of the delivery system that's glued on to a wire, and so we measure that joint as well.

Q. Did the G2 pass that test?

A. Yes.

MR. ROGERS: All right. Scott, if you would take that down, and let's go to 7.10. I'm sorry, not the document but in

that -- on that same page. Sorry about that.
BY MR. ROGERS:
Q. All right. Mr. Carr, do you see on your screen Section 7.10?
A. Yes.
Q. And can you describe for the jury what this test is?
A. So this is the filter migration test, which tests the cranial migration resistance of the device. The intention is to actually make the device migrate, and then we record the pressure, in this case, at which that occurs.
Q. And as we discussed on Friday, cranial migration would be migration toward the head; is that right?
A. That's correct.
Q. And it looks like you used various simulated size vena cavas over there on the left-hand side. Do you see that?
A. Yes.
Q. And can you tell the jury why that is?
A. So we tested the smallest, which is 15 millimeters, and then the highest indicated range, which is 28 millimeters. So we test the whole spectrum.
Q. And was one of the goals of the design of the G2 filter to improve cranial migration resistance?
A. Yes.
MR. ROGERS: All right. So let's go now to Section 7.10.3, which will be just below there, or over to the

next page. And can you pull that out, please.
BY MR. ROGERS:
Q. And so what do we see here, Mr. Carr?
A. You see a table of a summary of results.
Q. And so can you describe for the jury how this test was done?
Well, you've done that, but so -- over on the left-hand side, it looks like there are three different filter types; is that right?
A. Yes. The Simon Nitinol filter, the G1A or G2 filter, and the RNF, which is the Recovery filter.
Q. And why do we see three different filters here?
A. So the specification required that we compared to the SNF and the Recovery.
Q. And so what did these tests demonstrate?
A. That the G2 met its acceptance criteria.
MR. ROGERS: All right. Let's go to page 15. I guess we're there, but how about pull out Table 19, please. I guess that's where we just were; right? Okay.
Well, and to compare -- can you pull that back out, Scott? I'm sorry.
BY MR. ROGERS:
Q. But to compare the migration resistance of the G1A or the G2 to the Recovery, how did that compare from a relationship standpoint?

A. The G2 is almost double.

MR. ROGERS: All right. You can take that down.

All right. Let's now go to page 18, please. And pull out Section 7.11.

BY MR. ROGERS:

Q. Mr. Carr, what is this test?

A. This is the filter arm cyclic fatigue test.

Q. And can you describe for the jury, just generally, what the purpose of this test is.

A. So when we had observations of arm fracture with Recovery, we were able to see how that was happening. So the arm was being oriented in a way that we were then able to design and test with G2. So it was to compare the change we made from Recovery to G2 in this isolated controlled test.

Q. And would this test also be described as a saluting arm test?

A. Yes. We referred to it as that.

Q. And can you tell the jury just generally how this test works.

A. So we take the arm, so we would literally raise the arm up and you then cycle it or fatigue test it until it breaks. And so the change we made from Recovery to G2 was to change the orientation that -- what I refer to as the shoulder of the filter, where it came out of the top tube, and we tested that specific design change here.

Q. What was the change that you made to the shoulder from the Recovery to the G2?
A. We changed the curvature of how it came out of the sleeve. The Recovery had a pretty abrupt angle, whereas this was a more gentle curve.
Q. And were the two devices, the Recovery and the G2, compared side by side?
A. Yes.
Q. And why is that important?
A. Well, as a comparison test between the two. It wasn't a "must reach this number." It was how improved did we make the device.
Q. And so what did the results of the test demonstrate?
A. It was 12 times better, the G2 was.
Q. And so did the G2 pass this test?
A. Yes.
Q. And, Mr. Carr, if -- the jury has heard from a plaintiffs' expert named Dr. McMeeking about this test and was critical of it because he said that all it did was just test kind of the flapping of the arms, if you will. How do you respond to that?
MR. O'CONNOR: Objection. Calls for expert opinion.
THE COURT: Overruled.
THE WITNESS: That's exactly what the test did. It was designed to test the difference in the change that was made from Recovery to G2, and in a controlled way, we isolate that

change and test it appropriately. And so I would respectfully disagree with him.

BY MR. ROGERS:

Q. And if Mr. McMeeking is critical of this test because it didn't account for things like Valsalva maneuvers or coughing, how do you respond to that?

A. It wasn't intended to. It was intended to test this design change by itself.

Q. And if Dr. McMeeking claims that this testing does not actually show that the G2 was 12 times more fatigue resistant than Recovery, how do you respond to that criticism?

MR. O'CONNOR: Excuse me, Your Honor. Objection. Nondisclosure. They have an expert coming in.

THE COURT: Well, nondisclosure only applies to expert. Overruled. He's not appearing as an expert. He's describing what the company did.

MR. O'CONNOR: Thank you.

THE WITNESS: I'm sorry, could you repeat that?

MR. ROGERS: Sure.

BY MR. ROGERS:

Q. If Dr. McMeeking claims that the testing for the G2 does not actually prove that the G2 was 12 times more fatigue resistant than the Recovery, what is your reaction to that criticism?

A. I would disagree with him. The data shows that it is 12

times better in this test.

MR. ROGERS: All right, Scott. You can pull that down.

BY MR. ROGERS:

Q. And let's refer -- or move on to some other bench testing that is not design verification and validation testing.

Did Bard do other bench testing that doesn't fall into either of those categories?

A. Yes.

Q. And what is the reason why Bard did that?

A. We routinely do different tests to compare if we had an observation or different things as we develop new devices.

MR. ROGERS: All right. Scott, can we pull up Exhibit 5949, please.

BY MR. ROGERS:

Q. And, Mr. Carr, do you see this document in front of you?

A. Yes.

Q. And what are we seeing here, you and I?

A. It is a G2 filter clot trapping.

Q. And was this a test that you were involved in while you were an engineer at Bard?

A. I didn't do the test, but yes, I'm aware of it.

Q. And were you familiar with this report based on your experience at Bard?

A. Yes.

MR. ROGERS: Your Honor, I move this document into evidence.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit No. 5949 admitted into evidence.)

MR. ROGERS: May we display?

THE COURT: Yes.

BY MR. ROGERS:

Q. All right. So I guess to get ourselves oriented, Mr. Carr, tell us what the purpose of this test was, the clot trapping efficiency project.

A. It was to orient the filter in different ways to test its ability to trap clot.

Q. And do you know when this test was done?

A. Appears to be July of 2006.

Q. And was that after the G2 filter was on the market?

A. Yes.

Q. And so why was Bard conducting this test after the G2 was on the market as opposed to conducting it pre-market?

A. To learn about how it would work if it had tilted.

Q. And so why was that an important consideration?

A. Because the filter's main job is to trap clot and prevent it from going to the heart or lungs.

Q. And can you describe for the jury just generally how this test was done.

A. So you deploy the filter into a tube, and in this case we purposely tilted it or oriented it in different ways. And then you make certain sizes of clot, of actual blood clots, and you try and pass them through the filter and you measure the efficiency or how many of those clots it traps of a given size.

MR. ROGERS: All right. Scott, would you mind going to page 3 of the document, please?

And up here at -- can you pull out, yeah, the top part, 1.0.

BY MR. ROGERS:

Q. And can you read that, Mr. Carr?

A. Barely. I can --

Q. We're kind of pixel-challenged, it looks like, but what I wanted to bring to your attention is the last line there, does it indicate that the G2 filter was compared to the Greenfield filter?

A. Yes.

Q. And so why did Bard compare the clot trapping ability of the G2 filter when it was tilted to the Greenfield filter when it was tilted?

A. Because it was what we had originally compared to back in the Recovery filter also. It was even a gold standard of permanent filters at the time.

Q. And was there data that existed in the literature regarding the clot trapping ability of the Greenfield filter when it was

tilted?
A. Yes.
Q. So let's go to page 14, please.
And, Mr. Carr, I'm not going to try and pull this out because I'm afraid we'll lose the resolution, but we see several columns there. Can you tell us what we're seeing?
Did that make it worse?
A. Maybe. I can't read it very well.
It -- the things I can see, so it -- I believe it's testing at 0 degrees tilt, 20 degrees tilt, and 90 degrees tilt as you move from left to right.
MR. ROGERS: Thanks, Scott.
All right. Let's shrink that back down, if you don't mind. And pull out the Conclusion section.
BY MR. ROGERS:
Q. And, Mr. Carr, what were the results of this test?
A. That the mean clot trapping efficiency was greater than that of the Greenfield tilted in the straight tube.
MR. ROGERS: Okay. You can take that down, Scott. Thank you.
BY MR. ROGERS:
Q. Mr. Carr, I want to talk to you a little bit about the Simon Nitinol filter.
And there has been some suggestion in this case that the Simon Nitinol filter is a potential alternative design for

a doctor or a patient who wants to use a retrievable filter.

And based on your 20 years of experience working with IVC filters, do you think that the SNF is a reasonable alternative design to a retrievable filter?

MR. O'CONNOR: Objection. Calls for expert opinion.

THE COURT: Let's talk about that for a minute, counsel.

You can stand up if you'd like, ladies and gentlemen.

(At sidebar on the record.)

THE COURT: Mr. O'Connor, you want to explain that objection?

MR. O'CONNOR: Yes. He's asking him an expert opinion. He's going to an ultimate issue about the alternative design, and he's just asked Mr. Carr to give his opinion whether a filter was an appropriate alternative design. That's expert opinion in this case, clearly, and there was no disclosure on it and he has not been designated as an expert.

THE COURT: I'm sorry. Was there more?

MR. O'CONNOR: No, that's --

THE COURT: What's your response, Mr. Rogers?

MR. ROGERS: First of all, Your Honor, I think it satisfies Rule 701, that it's rationally based on the witness's perception as a lay witness. This is lay witness opinion testimony.

And it's helpful to clearly understand the witness's

testimony or determining fact issues. And it's not based on scientific, technical, or other specialized knowledge.

THE COURT: Why is it not? You specifically said: Based on your 20 years of experience --

MR. ROGERS: Right.

THE COURT: -- what is your opinion?

MR. ROGERS: Yes, Your Honor.

THE COURT: You're clearly calling for an opinion based on specialized knowledge, aren't you?

MR. ROGERS: Yeah, I would agree, Your Honor.

THE COURT: So I'm going to sustain the objection. And the fact that it's given by a nonretained expert doesn't eliminate the disclosure obligation under Rule 26(a)(2)(C) --

MR. ROGERS: Understood, Your Honor.

THE COURT: -- which applies to employees.

Just so we don't come back on this, my view is that if he's describing what the thinking was within Bard, what the purpose of the test was within Bard, why Bard thought a particular test was appropriate, which I think were the questions I overruled you on, I think that's fair because that's what Bard was doing.

But if you're asking him based on his experience to give an opinion that is contrary to the experts, I think that's Rule 702 opinion.

MR. ROGERS: Understood, Your Honor.

THE COURT: So you need to cast it in the context of what Bard did, what Bard's thinking was, what his intent was at the time. That's factual testimony.

MR. ROGERS: Okay. Understood. Thank you, Your Honor.

MR. O'CONNOR: But there is going to be a problem with that, because I don't think there's going to be any foundation for a comparison between the Simon Nitinol filter and its history and the G2 and what happened. I mean, they're going to take the position that the Simon Nitinol filter ultimately was not the predicate device for the G2, that it was the Recovery.

THE COURT: Well, they can testify to the facts on those points. You might disagree with them, but they can give that factual testimony.

MR. O'CONNOR: Okay.

MR. ROGERS: Thank you, Your Honor.

(End of discussion at sidebar.)

THE COURT: Thank you, ladies and gentlemen.

BY MR. ROGERS:

Q. All right, Mr. Carr. We're going to proceed.

The Simon Nitinol filter, let me ask you a few more questions about it. Was it a permanent-only filter?

A. Yes.

Q. And would doctors have been able to retrieve that filter percutaneously?

A. No.
Q. And in your experience while you were an engineer at Bard and at NMT prior to that, what were the types of patients who typically received a Simon Nitinol filter?
A. So they were typically older, nearing end of life, probably, and -- or just a patient who had no real opportunity or ever a need to not require a filter. So...
Q. And does Bard still sell the Simon Nitinol filter in the United States today?
A. No, we don't.
MR. ROGERS: All right. Can we pull up Exhibit 7900, please.
BY MR. ROGERS:
Q. Mr. Carr, can you see that?
A. Yes.
Q. And can you identify for the record what that is.
A. It is the sales of our, Bard's, retrievable filters and the SNF filter.
Q. And are you familiar with this document based on your work at C.R. Bard as an engineer?
A. Yes.
MR. ROGERS: Your Honor, I move this into evidence.
THE COURT: This is 7900? Is that right?
MR. ROGERS: Yes.
MR. O'CONNOR: Objection, Your Honor. 602.

THE COURT: I think additional foundation is needed.
BY MR. ROGERS:
Q. Mr. Carr, in your work at Bard as an engineer, did you get sales data for the various filters?
A. Yes.
Q. And were you familiar with the sales data for the Simon Nitinol filter?
A. Generally, yes.
Q. And were you familiar with the sales data for the Bard retrievable family of filters?
A. Yes.
MR. ROGERS: Your Honor, I move this into evidence.
MR. O'CONNOR: Yeah, no objection for demonstrative purposes.
THE COURT: This is being moved into evidence.
MR. O'CONNOR: Pardon me?
THE COURT: I thought you moved it into evidence, Mr. Rogers.
MR. ROGERS: That's correct, Your Honor.
THE COURT: It's being moved into evidence. It's not being used as a demonstrative.
MR. O'CONNOR: Objection, Your Honor. 602. And this really is a summary and a demonstrative, so objection to its admission into evidence.
THE COURT: I'm going to overrule the 602 grounds. I

don't believe the other objection is founded in the rules of evidence, so I'm going to admit Exhibit 7900.

(Exhibit No. 7900 admitted into evidence.)

MR. ROGERS: May we display, Your Honor?

THE COURT: You may.

BY MR. ROGERS:

Q. Mr. Carr, can you describe for the jury what this -- what this chart or -- if that's the correct word -- what this document shows?

A. Yes. So the orange or red line shows the sales of retrievable filters from 2003 to 2016, September, as well as the SNF or Simon Nitinol filter sales in blue on mine over the same time frame.

Q. And based on your experience as a C.R. Bard employee, why were the Simon Nitinol sales low compared to the sale of the retrievable filters?

A. Because when optional or retrievable filters began coming to the market, also being permanent, the need for a permanent-only filter was declining over time.

Q. Mr. Carr, are you aware of any IVC filter that is on the market today that does not have reports of filter fracture?

A. No.

MR. ROGERS: And, Scott, you can bring this down. I'm sorry.

BY MR. ROGERS:
Q. And are you aware of any IVC filter that's on the market today that does not have reports of filter migration?
A. No.
Q. And are you aware of any IVC filter that's on the market today that does not have reports of filter penetration?
A. No.
Q. And are you aware of any IVC filter on the market today that does not have reports of filter perforation?
A. No.
Q. And let me ask you about long-term studies in humans, because the jury has heard about that.

Are you aware of any clinical study that has been conducted on a retrievable filter that lasted more than five years?
A. No.
Q. And are you aware of any clinical study in humans on a permanent IVC filter that has been conducted for more than five years?
A. No.
Q. And I believe you also told us on Friday that you worked at NMT; is that right?
A. Yes, I did.
Q. And when you were there, was a study done, a clinical study in humans, on the Simon Nitinol filter?

A. It was before I arrived.
Q. But you were familiar with that through your work there?
A. Yes.
Q. And how long was that study?
A. That was followed to 180 days.
Q. And, Mr. Carr, if there are reports of fracture with the G2X filter or the Eclipse filter, why does Bard continue to market these filters?
A. Because they -- the reported rates are exceptionally low, and the benefit that that product -- those devices provide patients far outweighs the relative risk to them.
Q. And, Mr. Carr, how long have you been working in the area of IVC filters?
A. 21 years.
Q. And is that the majority of your entire career?
A. Almost, yes.
Q. And, Mr. Carr, was there any point at your experience at either NMT or at C.R. Bard where you felt that there was some rush to market to get a filter out there that would have compromised the development process?
A. No.
Q. Mr. Carr, do you hold any patents for IVC filters?
A. Yes.
Q. And are you familiar, based on your work at C.R. Bard, with the amount of money that is spent on the research and

development of IVC filters?
A. Yes.
Q. And are you also familiar with the amount of money that is spent at C.R. Bard on the marketing of IVC filters?
A. Yes.
Q. And how do you -- how do those two things compare from a relationship standpoint?
A. The money spent on R&D is three to four times the money that's spent in marketing.
MR. ROGERS: All right. Thank you, Mr. Carr. I don't have any further questions for you at this time.
THE COURT: Cross-examination?
MR. O'CONNOR: Your Honor, may we approach for one moment, please?
THE COURT: Yeah. Does this concern the three exhibits you want admitted?
MR. O'CONNOR: Well, we have that. No, this is an issue about --
THE COURT: Yeah. You can come forward.
Again, feel free to stand up.
(At sidebar on the record.)
MR. O'CONNOR: I'm going to let Mr. Lopez take this.
MR. LOPEZ: Your Honor, on Friday Mr. Carr was answering questions about the Recovery filter and his total product life cycle to make it, and he was painting the

impression that it was a natural course of what this company does as a good company, that they're always looking to improve their device and that's why they came out with the G2, just to deal with, you know, migration and fractures, if it's just something that happens and that we have to now move on, like a good company, and now redesign it and come out with a better product.

And he brought them all through that's what this company does is this company -- it's not about the device being unsafe or killing people; it's about what a good company, any good company, would do to continue to enhance its products.

Well, that is a farce. I mean, the reality of what happened and why there was -- this G2 was on the market and designed is because this company was in a crisis mode and they were panicked about what was going to happen in the marketplace with their reputation. And one of the reasons why the G2 failed the way it failed is because they didn't -- they overdesigned this thing so it wouldn't have had this cephalad migration issue anymore. That's the story. That's what happened.

This jury is left with the impression after Mr. Carr testified that this is just a normal, natural thing of a progression from the Recovery to the G2, just them trying to, you know, make the product a little bit better than the product they had before.

It's just not fair for us, Your Honor, for that story to be left with this jury without us having an opportunity to really describe what was going on. It wasn't because this company was looking to do the right thing, a good thing, and what any good company would do. They were --

THE COURT: Let's not repeat. I understand your point. Let me ask you a question.

MR. LOPEZ: Sure.

THE COURT: My memory is that in one of the iterations of the cephalad migration ruling, you made the argument that you couldn't tell the story of the problems with the Recovery filter, the rush to market, et cetera, without mentioning cephalad migration deaths.

And I had you actually submit documents and testimony to address whether or not you could do that, whether you could tell that story without mentioning deaths.

And after looking through that evidence, I concluded that you could tell the story of what you characterize as the rush to market.

I have two questions. I don't trust my memory, so my first question is whether I'm wrong on that or whether I dreamed that. I don't think I did, but assuming I did, the question then would be, what's different? Why can't you now tell the story that you think is the accurate story without mentioning the cephalad migration deaths that ended with the

Recovery?

MR. LOPEZ: Because I think it completely changes the company's mindset on -- I mean, look, it took them seven years to put caudal anchors on the G2 to make it caudal resistant. They were in a complete -- they wanted to submit this 510(k) to FDA in -- before the end of 2004. In fact, they tried to do it in early 2005.

But, again, it's not -- we can tell the story a little bit. I mean, we wish we could really give the jury the reality of what really happened.

But when Mr. Carr testifies that this is just a good company doing the right thing by, you know, just looking to improve a product that they just had on the market because that's what a good company does when it created the G2, that's not what happened, Judge. That's just not the facts.

THE COURT: I know that's your point, but I guess what I'm asking in the questions I just asked is, why can't you address that in cross-examination and argument and say to the jury what you just said to me?

MR. LOPEZ: Without telling the jury about the deaths?

THE COURT: Yeah. I mean, that's the issue that I remember addressing specifically, was whether you would be unable to tell that story without mentioning the deaths.

And after looking at the evidence you submitted, I concluded that you would not be unable to do it. You could

still bring together the timeline. You could bring together memos reflecting the crisis. You could bring together failure rates on the Recovery. You could do all of that without mentioning the cephalad migration deaths that ended with the Recovery.

I mean, am I misremembering that, or did we go through that exercise?

MR. LOPEZ: You're trusting my memory, too, but --

THE COURT: Fair.

MR. LOPEZ: Of course that's the discussion we had. I mean, I agree with that. That's generally what we talked about.

And we were prepared to have to do that based on your recent ruling, but I just hate having to sit here time and time again and listen to them downplay what was really going on with the Recovery to their benefit. And we can't counter that with what really was going on.

I know it seems a little subtle, but when you pile it on and with the evidence that the Recovery was just -- you know, hey, we tested it. We did all these -- they put in all these tests they did on the Recovery, and then Mr. Carr talks about this total product life cycle and that they were just doing what any great company would do, I mean, that's just -- that's just -- it's unfair.

It doesn't give us -- it doesn't really give our

client the right -- I mean, a fair trial on that issue. Because I don't know what the jury's thinking about that. They're probably thinking, well, you know, the product's only been on the market a couple years, they had a few little hiccups, and look what they did. They did all this wonderful testing of the G2. It's 12 times greater fracture resistant. And, you know, they did what any good company would do and they made the product a little better.

I mean, for us to not be able to really show the jury, no, no, that's not what actually happened. What happened is this company was in a complete panic and they needed to rush a thing to market was based on people were dying.

And you know what? They left it on the market. This is not a good company doing the right thing and making a good product. No, this was a company that left their product on the market until the G2 was ready to be launched as 17 people died in the process. I don't -- I think it's unfair that this jury doesn't get to know that.

Anyway --

THE COURT: Okay. I understand that point.

MR. ROGERS: Your Honor, I disagree. I think that this is exactly what your MIL ruling on this issue addressed. And as I understand it, you know, the plaintiffs can, as you said, if they want to cross-examine our witnesses on issues with the Recovery, they can do that. I think, as I understand

it, they can raise cephalad migration problems. They just can't go into death.

And I think if that's the story they want to try to tell, they can try and do that with cross-examination. And there is a remoteness to when Mrs. Hyde received her filter in 2011 and the time period that Mr. Lopez wants to explore in 2003.

And as Your Honor has looked at in several different iterations of this, there's -- we have not seen any evidence of any migration deaths via cephalad migration with any of these later iterations of filters. And I think it would be highly prejudicial to determine that this opened the door.

THE COURT: All right. Well, I think this is ground we covered before. I think I ruled that plaintiffs could tell the story without mentioning deaths.

I will go back and reread those orders in light of what you argued, Mr. Lopez, to see if I think I was inaccurate in them. But I do think this is the ground we covered before.

You have absolutely the right to go into the rates of failures with Recovery, the discussions about pulling it from the market, the evidence that you think shows a crisis mode, the rush to market, all of that. And even, as I pointed out, that particular failure modes could potentially lead to death.

What I've excluded are the 17 deaths under Rule 403 for reasons that I went into in length in my previous orders.

So I'm going to stand on that decision. I will look at those previous orders.

MR. LOPEZ: I just want to make one more statement.

The point I'm trying to make is that they're taking advantage of that ruling, I mean, to our detriment and to their advantage. They've done it over and over again. They did it in the last trial, and they're doing it in this trial.

They're taking advantage of the fact that we can't counter testimony from Mr. Carr about what he just said about this natural progression. They're taking advantage of it, and it's unfair that they're allowed to do that knowing that you've ruled that we can't counter that story with what the reality of the facts are.

That's the main reason we're up here. We're not up here because we -- you know, we just feel like we want to re-urge you to reconsider something. We're up here because they're taking undue advantage of your ruling on that issue, and it's just -- it's just not fair.

And, I mean, if they do it again, we're going to be back up here and ask you to reconsider again. Because I wouldn't be here unless Mr. Carr said what he said.

THE COURT: Okay. I understand that point.

Now, are you going to move into evidence three exhibits?

MR. LOPEZ: Yeah. Want us to do that now, Judge?

THE COURT: Yeah.

Are you going to have any objection to those three exhibits?

MR. ROGERS: No, Your Honor. We already --

MR. LOPEZ: 4767, 4768, and 4775.

MS. HELM: No objection, Your Honor.

THE COURT: Okay. Let's go ahead and have whoever's up move those in before we -- that's fine.

MR. LOPEZ: I'll do it, Judge.

THE COURT: That's fine.

(End of discussion at sidebar.)

THE COURT: Thank you, ladies and gentlemen.

MR. LOPEZ: May I, Your Honor?

THE COURT: Yes.

MR. LOPEZ: Just a housekeeping issue before Mr. O'Connor gets up for his cross-examination.

On the -- plaintiffs are moving into evidence exhibits that came in through Dr. Kuo's deposition. That's Exhibit 4767, 4768, and 4775. We offer those into evidence at this time.

MS. HELM: No objection, Your Honor.

THE COURT: All right. Those are admitted.

(Exhibit Nos. 4767, 4768, and 4775 admitted into evidence.)

THE COURT: And you may proceed, Mr. O'Connor.

MR. O'CONNOR: Thank you, Your Honor.

CROSS-EXAMINATION

BY MR. O'CONNOR:

Q. Good morning, Mr. Carr. Again, I'm Mark O'Connor. How are you this morning?

A. I'm well, thank you. Good morning.

Q. I want to talk about something that you have testified previously just so -- and make sure we're clear on this.

The Recovery, the G2, and the G2X should perform as well as permanent filters. True?

A. Again, they perform differently in certain cases; and in certain cases, yes.

MR. O'CONNOR: All right. Felice, would you put up November 5, 2013, at page 41.

BY MR. O'CONNOR:

Q. Mr. Carr, you were involved in depositions, including one in November of 2013.

Do you recall that?

A. I don't see a date, no.

Q. We can go to the first page if you'd like.

A. Yes.

MR. O'CONNOR: And, Felice, if you go to page 41.

BY MR. O'CONNOR:

Q. And at page 41, line 11, you were asked the following question: Sir, would you agree that optional filters -- the

Recovery, the G2, the G2 Express -- should perform as well as permanent filters?

And your answer was: Yes.

Now, did I read that correctly?

A. Yes.

Q. Thank you.

MR. O'CONNOR: Stay there, Felice.

BY MR. O'CONNOR:

Q. And as a matter of fact, Mr. Carr, you agreed then that the Recovery, the G2, and the G2X were truly permanent filters. True? Back at that time.

A. All of them, yes.

Q. Thank you.

A. Uh-huh.

Q. And you also agree that retrievable filters should be at least as safe as the permanent ones; correct?

A. I think that all filters should be safe and effective.

Q. My question is different.

The retrievable filters at Bard should be as safe as the permanent filters; correct?

A. They should all be safe and effective.

Q. Do you agree, Mr. Carr, that the Asch study did not support that the Recovery filter and the G2 filter were appropriate for permanent use?

A. Do I support that?

Q. Do you agree that the Asch study did not support the Recovery being used as a permanent filter?
A. No, I don't.
MR. O'CONNOR: Felice, let's go to his deposition, December 19th, 2013, at page 154.
Excuse me one second, Mr. Carr.
BY MR. O'CONNOR:
Q. The question to you, sir, at line 8 was: It's your testimony that the Asch study supports the contention by Bard that the Recovery and G2 devices are appropriate for permanent use; true?
And your answer was: No.
Now, did I read that correctly?
A. You did.
Q. Thank you.
A. And if you read down lower, you can see the further conversation.
Q. Well, sir, did I read the testimony I just cited to you correctly? Yes or no, please.
A. Yes.
Q. Thank you.
MR. O'CONNOR: Felice, let's go to -- excuse me one second -- Exhibit 4554.
BY MR. O'CONNOR:
Q. And, sir, you testified that you were at NMT before coming

to Bard; correct?
A. Yes.
Q. And you were there on May 22, 2000; true?
A. Yes.
MR. O'CONNOR: Move for the admission of 4554.
MR. ROGERS: No objection, Your Honor.
THE COURT: Admitted.
(Exhibit No. 4554 admitted into evidence.)
MR. O'CONNOR: And, Felice, if you would go to page 7, please.
And may I publish to the jury, Your Honor?
THE COURT: Yes, you may.
BY MR. O'CONNOR:
Q. And, Mr. Carr, this is the time that Bard was in discussions with NMT about the Recovery and the Recovery technology; correct?
A. This is a presentation to Boston Scientific.
Q. But, again, Bard eventually purchased the Recovery filter; correct?
A. Ultimately, yes.
Q. And at the time of this document, if you look at --
MR. O'CONNOR: The last bullet point in the box, Felice.
BY MR. O'CONNOR:
Q. What NMT was representing at that time about the Recovery

filter was that it was removable at 12 weeks; correct? Do you see that? Did I read that correctly, that last bullet point?
A. Yes, but we weren't representing that. This is a --
Q. Did I read that statement correctly, "removable at 12 weeks"?
A. Yes.
Q. Thank you.
MR. O'CONNOR: And, Felice, go to Exhibit 553.
BY MR. O'CONNOR:
Q. Do you recognize this document? It is the Recovery Compassionate Use dated September 14, 2000. You can see your name is copied there.
A. I haven't seen it in a long time.
Q. You see it now; correct?
A. I do.
Q. And you see your name on it; true?
A. I do. I'm cc'd.
MR. O'CONNOR: Move to admit 553.
MR. ROGERS: Your Honor, I believe it may already be in.
THE COURTROOM DEPUTY: It is.
THE COURT: Yes, it is already in evidence.
BY MR. O'CONNOR:
Q. Mr. Carr, this document --
MR. O'CONNOR: May I display to the jury, Your Honor?

THE COURT: You may.

BY MR. O'CONNOR:

Q. This document was prepared during the time of Dr. Asch's retrievability study; is that correct?

A. Yes.

Q. And the -- one of the issues that was addressed --

MR. O'CONNOR: Can we go to page 2, Felice.

BY MR. O'CONNOR:

Q. One of the issues that was addressed at that time was that a patient in the study group had experienced migration. True?

A. I don't see that in the document, no.

Q. But you do recall that; correct? There was a patient who had experienced migration?

A. Yes, but I don't know what this document is so...

Q. All right. I'm asking you separate from this document.

A. Sorry.

Q. Is it fair to say there were patients that experienced complications, and there was a patient that was discussed who experienced migration; true?

A. There was a patient who had a migration, yes.

MR. O'CONNOR: And, Felice, if you would highlight number 4, please.

BY MR. O'CONNOR:

Q. And let me read this statement in the memo.

It was established that if (1) the filter moved 4 CM

(one filter length) or the filter moved to a suprarenal location, the compassionate use experience would be immediately stopped and the filter design challenged.

Now, did I read that correctly, Mr. Carr?

A. Yes.

Q. And the statement goes on to stay: Filter implants would be halted, but filter removals of indwelling filters would continue until all remaining filters were removed.

Did I read that correctly, sir?

A. Yes.

Q. Eventually, the Recovery was cleared and launched into the market; correct?

A. Yes.

Q. And when it was originally launched, it was promoted as a permanent filter first; correct?

A. Yes.

Q. And by the way, it was eventually -- the Simon Nitinol filter was the predicate device for the Recovery filter; correct?

A. It was a predicate. There were two.

Q. All right. One of the predicates.

And the Simon Nitinol filter was a permanent filter; correct?

A. Yes.

Q. And the Recovery was designed and promoted to be a

permanent filter; true?
A. Yes.
Q. It was -- and after the Recovery was on the market for a while, it was eventually cleared with the retrievable indication; true?
A. Yes.
Q. But Bard did nothing to change the original design of the Recovery during that period of time; correct?
A. Which period of time?
Q. From the time it was launched as a permanent device to when it was cleared as a retrievable, there were no changes to the Recovery design; correct?
A. Yes.
MR. O'CONNOR: Let's go to Exhibit 1219.
BY MR. O'CONNOR:
Q. This is a health hazard evaluation. And these are the types of evaluations that are prepared at Bard; is that correct?
A. Yes.
MR. O'CONNOR: Move to admit 1219 into evidence, Your Honor, as redacted.
MR. ROGERS: No objection, Your Honor.
THE COURT: Admitted.
(Exhibit No. 1219 admitted into evidence.)

BY MR. O'CONNOR:
Q. And, Mr. Carr, when the Recovery was being used on the market, it started experiencing events and failures that were to the level of being catastrophic; correct?
A. The -- excuse me?
Q. The Recovery, in patients, patients were experiencing serious injuries, catastrophic events. Do you agree with that?
A. Yes.
MR. O'CONNOR: And may we publish, Your Honor?
THE COURT: Yes.
BY MR. O'CONNOR:
Q. And as you can see, sir, as of June 30, 2004, Dr. Ciavarella had prepared an updated health hazard evaluation.
Do you see that?
A. No.
Q. You don't see that Dr. Ciavarella sent that to Doug Uelmen?
A. Yes, I do. Thank you.
Q. And Dr. Ciavarella was the medical director; correct?
A. He was at one point, yes.
MR. O'CONNOR: And, Felice, if we could highlight that first paragraph.
BY MR. O'CONNOR:
Q. And the jury will be able to receive this, but -- to review this themselves, but this talks about, the first sentence:

Migration of thrombus-encased Recovery inferior vena cava filter has been reported in 10 patients.

And that's as of June 30, 2004; correct?

A. That's the date of the document, yes.

Q. And go to the Conclusion.

And the Conclusion was: The severity category for the risk of thrombus-associated filter migration is catastrophic.

Did I read that correctly?

A. Yes.

Q. All right. Thank you.

A couple questions about the saluting arm test.

MR. O'CONNOR: We can take that down, Felice.

BY MR. O'CONNOR:

Q. The saluting arm test is not a general fatigue test. Do you agree with that?

A. I don't know what that means.

Q. Well, it only measures the situation where the arm is moving up and down; correct?

A. Yes. That's what it was designed to do.

Q. And is that the situation where the G2 proved to be better than the Recovery?

A. Yes, in that test.

Q. Okay. But you did not test the G2 in that test against the Simon Nitinol filter?

A. The Simon Nitinol filter can't behave that way. It can't

fail that way, so no, we didn't.

Q. Thank you.

Mr. Carr, Bard eventually took the Recovery filter off the market; correct?

A. It was replaced by G2, yes.

MR. O'CONNOR: And if we could, Felice, let's go to Exhibit 755.

BY MR. O'CONNOR:

Q. And you do recall Janet Hudnall and the special accounts roadshow; correct?

A. Yes.

Q. And you are the person that Bard has designated most familiar about documents, including documents generated and maintained in the course of Bard's business; correct?

A. I have been for different things. I don't know specifically.

MR. O'CONNOR: Move for admission of 755, Your Honor.

MR. ROGERS: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit No. 755 admitted into evidence.)

BY MR. O'CONNOR:

Q. And this -- the period of this roadshow was in about -- well, according to this email, this email is dated March 9, 2005.

MR. O'CONNOR: I'm sorry, Your Honor. May I publish

to the jury?

THE COURT: You may.

BY MR. O'CONNOR:

Q. Do you see the date there, March 9, 2005?

A. Yes.

Q. And the roadshow was where Janet Hudnall was going to visit important accounts, doctors and other customers of Bard; true?

A. She went to visit accounts.

Q. And she went to visit accounts and wanted to talk about the experiences with the Recovery as well as the new G1A Recovery, which would become the G2 filter; true?

A. I believe so, yes.

Q. And we can show examples of this priority account document.

MR. O'CONNOR: Felice, if you would go to page 14.

BY MR. O'CONNOR:

Q. And what Janet Hudnall did, Mr. Carr, is she went and visited accounts, as you told us, and she received comments and information about experiences doctors had had with the Recovery filter; true?

A. I don't know what she did.

Q. Well, we can look.

For example, she saw Dr. Reifsnyder. Do you see that?

A. No, I don't.

Q. Right on top.

MR. O'CONNOR: Show Mr. Carr where that's located,

Felice, please.

BY MR. O'CONNOR:

Q. He was a doctor in Austin, Texas. Do you see that?

A. This document does not show who she went to see.

Q. All right. Well, on this priority accounts document that we now have into evidence, you see where there is Drs. Reifsnyder to the left.

Do you see that?

A. I do.

Q. And you see where there is a hospital named Brackenridge Hospital.

Do you see that?

A. I do.

Q. And you see that it's in Austin, Texas; right?

A. I do.

Q. And you also see under the column entitled Annual Volume, $200,000.

Do you see that?

A. Yes.

Q. And you see the comment: Heard of migration and won't use.

Do you see that?

A. I do.

MR. O'CONNOR: All right. And, Felice, if we could go to number 9.

BY MR. O'CONNOR:
Q. And, sir, over to the right she saw another account and wrote the comment: Account has stopped using due to several reported complications.
Do you see that?
A. I do, but she did not see the account. That is not what this document says.
Q. Sir, did I read the comment correctly?
A. You did not introduce the comment correctly. She did not visit the site.
Q. Okay. Sir, this is a priority account document generated at Bard; correct?
A. By the Western regional manager.
Q. All right. Thank you for that clarification.
And it was prepared by somebody within Bard; correct?
A. Yes.
Q. And it recorded comments from doctors; true?
A. No.
Q. Okay. There are comments in the right-hand column; correct?
A. There are.
Q. And I read those comments; correct?
A. You did.
Q. All right. And we could go through this, and we could see several comments that would be just to the right of doctors who

are identified and their location in the Western Region; true?
A. Yes.
MR. O'CONNOR: And if we go to page 17. And, Felice, go to number 8.
BY MR. O'CONNOR:
Q. And we can go through all these, Mr. Carr. I'm just showing you examples.
But you see the comment to the right: Stopped using, migration.
Did I read that correctly?
A. Yes.
MR. O'CONNOR: Okay. And, Felice, go to the one just below.
BY MR. O'CONNOR:
Q. The comment there is: Concerned over bad press.
Did I read that correctly?
A. Yes.
MR. O'CONNOR: And, Felice, go to number 11.
BY MR. O'CONNOR:
Q. Stopped using.
Did I read that correctly?
A. Yes.
Q. And you understood this was referring to the Recovery filter. True?
A. Yes.

Q. Thank you.

MR. O'CONNOR: Let's go to Exhibit 1616, Felice.

BY MR. O'CONNOR:

Q. This is a Bard document entitled Patient Questions & Answers.

Do you see that?

A. Yes.

MR. O'CONNOR: Move for admission of 1616, Your Honor.

THE COURTROOM DEPUTY: It is in evidence.

THE COURT: That's already in evidence, Mr. O'Connor.

MR. O'CONNOR: All right. Thank you.

Felice, let's go to page 6. Can you enlarge that?

BY MR. O'CONNOR:

Q. And what Bard did was it inserted a question that may be asked by a patient. Do you see down at the bottom where I'm reading?

The question is: When can the filter be removed? Is there a cutoff date by which the filter must be removed?

MR. O'CONNOR: Oh, may I publish, Your Honor?

THE COURT: You may.

MR. O'CONNOR: Thanks.

BY MR. O'CONNOR:

Q. And again, we're talking about a patient question and answer document, Mr. Carr, that was prepared by Bard; correct?

A. Yes.

Q. And let me just read this question that Bard placed in this document: When can the filter be removed? Is there a cutoff date by which the filter may be removed?

Did I read that question correctly?

A. Yes.

Q. And the answer is: The G2 does not have a time limit in which it must be removed. The filter can be removed at any time after the point at which you no longer need it. This is up to your physician.

Did I read that correctly?

A. Yes.

Q. Mr. Carr, earlier you talked about the tilting test that was done after the G2 was on the market. Correct?

A. Yes.

Q. And by that time, the G2 had been implanted in patients; right?

A. Yes.

Q. And Bard had received reports of the G2 filter tilting, perforating, fracturing, and migrating in patients; true?

A. I don't know.

Q. You don't recall any of that?

A. I don't know if we had received complaints of all of those at that time.

Q. Well, would you dispute any testimony that's come into this case as to when complaints about G2 tilting was occurring?

A. No.
Q. You talked about the migration-resistant tests for the G2, and I think you described that as cranial migration; correct?
A. We reviewed that, yes.
Q. And that's migration going up; true?
A. Yes.
Q. And that was the tests where you used the 15-millimeter diameter simulation of the vena cava diameter; right?
A. That was one of the diameters.
Q. What you do know as you are here today, that Bard did receive complaints of the G2 migrating downward. True?
A. We have, yes.
Q. And you do know as you sit here today that Bard did receive complaints of the G2 fracturing; correct?
A. Yes.
Q. And the same with the Eclipse. You did receive reports of the Eclipse caudally migrating; correct?
A. I don't know for sure, but probably.
Q. And you do -- and are aware of reports of the Eclipse filter fracturing; true?
A. Yes.
MR. O'CONNOR: I think that's all I have, Your Honor. Thank you.
THE COURT: All right. Redirect.

REDIRECT EXAMINATION

BY MR. ROGERS:

Q. Mr. Carr, I want to follow up with just a few things that were just covered with you by plaintiffs' counsel.

MR. ROGERS: Can we get Exhibit 553 back, please?

And can you go to the following page, paragraph 4.

Your Honor, may I display?

THE COURT: Yes.

BY MR. ROGERS:

Q. Mr. Carr, you were just asked some questions about this document and the possibility of stopping this study if there was a migration.

Do you recall that?

A. Yes.

Q. And was the Asch study that was conducted, was it stopped?

A. No, it was not.

Q. And why is that?

A. Because we did not observe another -- one of the reasons, we did not observe a second filter migration in the study.

Q. And the study that Dr. Asch was doing, what filter was it about?

A. The Recovery filter.

MR. ROGERS: And, Scott, can you take that down and go to the prior page, please.

BY MR. ROGERS:
Q. And, Mr. Carr, what's the date of this document?
A. September 14th, 2000.
Q. All right. Thank you.
MR. ROGERS: You can take that down, please.
And can you pull back Exhibit 1219.
May we display, Your Honor?
THE COURT: You may.
BY MR. ROGERS:
Q. Mr. Carr, do you recall plaintiffs' counsel asking you questions about this document?
A. Yes.
Q. And what is the date of that document?
A. June 30th, 2004.
Q. And what filter does this document concern?
A. The Recovery filter.
MR. ROGERS: All right. And can we go to the Conclusion section on the following page. Following page -- oh, I'm sorry. There we go.
BY MR. ROGERS:
Q. And you got asked questions about this and whether this issue was -- that was discussed in this memo is catastrophic.
Do you remember that?
A. Yes.
Q. And what is the frequency category for this complication?

A. It is remote or about 0.5 percent.

MR. ROGERS: Thank you. You can take that down.

And can you pull back Document 755, please.

BY MR. ROGERS:

Q. And you were asked about this email chain.

Do you recall that, Mr. Carr?

A. Yes.

Q. And what is the date of this document?

A. The last email is March 9th, 2005.

Q. And this was the document that contained the list of the special accounts; is that right?

A. Yes.

Q. And what filter were those comments about?

A. I believe the Recovery only.

MR. ROGERS: May we display, Your Honor?

THE COURT: You may.

BY MR. ROGERS:

Q. And, Mr. Carr, were the design changes that were made from the Recovery to the G2, was one of the things that they were intended to address was to improve the resistance of cranial migration?

A. Absolutely.

Q. And did the testing of the G2 filter bear out that it had indeed improved cranial migration resistance?

A. Yes. It almost doubled.

Q. And, Mr. Carr, what is your best recollection of when the G2X filter was cleared?
A. It would be a total guess. I don't know. I'm sorry.
Q. All right. And, well, how about with the Eclipse filter? What is your best guess, I mean, approximately what was the time period when the Eclipse filter was cleared?
A. Again, I don't know for sure. I think 2009, '10 time frame.
Q. Okay. And all of that would have happened some five years, six years before any of the documents that we just reviewed?
A. After, you mean?
Q. Yes, sir.
A. Yes.

MR. ROGERS: Okay. Thank you. No further questions.

THE COURT: All right. Thanks. You can step down.

(Witness excused.)

MR. ROGERS: Your Honor, at this time the defendants call Shari Allen O'Quinn.

THE COURTROOM DEPUTY: Ma'am, if you'll please come forward and raise your right hand.

(The witness was sworn.)

THE COURTROOM DEPUTY: Please state your name and spell it for the record and the jury.

THE WITNESS: My name is Shari O'Quinn, S-H-A-R-I, O'Quinn, O, apostrophe Q-U-I-N-N.

THE COURTROOM DEPUTY: Thank you, ma'am. Please come have a seat.

SHARI O'QUINN,

called as a witness herein by the defendants, having been first duly sworn or affirmed, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. ROGERS:

Q. Good morning.

A. Good morning.

Q. How are you?

A. Good. How are you?

Q. Good.

Can you state your name for the jury, please?

A. Yes. It's Shari O'Quinn. Formerly known as Shari Allen.

Q. And was there a time that you worked at C.R. Bard?

A. Yes.

Q. And how long did you work at C.R. Bard?

A. Approximately four years, from 2003 to 2007.

Q. And when you were working at C.R. Bard, what was the last name that you were using at that time?

A. Shari Allen.

Q. And what division of C.R. Bard did you work for?

A. Bard Peripheral Vascular.

Q. And can you describe for the jury generally what your position was when you were at C.R. Bard.

A. Yes. I was the director of clinical and regulatory affairs. And I led the teams who conducted the clinical studies and also filed the registrations with the regulatory agencies to get the products approved.
Q. And so what sorts of projects did you work on when you were at Bard?
A. We had a number of projects, including, of course, the vena cava filters, vascular stents and stent grafts, and a number of biopsy and angioplasty products.
Q. And during the time period that you were at Bard, what were the filters that you worked on yourself?
A. Personally, I worked on the Recovery filter and the G2 filter.
Q. And did you ever work on the G2X filter?
A. No, I did not.
Q. Did you ever work on the Eclipse filter?
A. No.
Q. Can you describe for the jury, please -- let me -- I'll get to that in a second. Let me ask you a few more background questions.
Can you tell the jury where you grew up?
A. Yes. I grew up in Virginia.
Q. And where do you live now?
A. I live in Arizona. I live in Carefree. I've been here for almost 15 years.

Q. And where do you work presently?
A. I work presently for W.L. Gore and Associates. They're based here in Arizona.
Q. And what type of company is that?
A. It's very similar. It's a cardiovascular medical device company.
Q. How long have you been working in the medical device industry?
A. I started in 1992 in research and then started in industry in 1994.
Q. And have you always been in the regulatory part of the industry?
A. Regulatory and clinical. I've worked in both.
Q. What is your current position at W.L. Gore?
A. My current position is called medical functions leader. And it's leading all of the functions related to -- specifically to a medical company, like clinical, regulatory, medical affairs, and also the quality.
Q. And can you describe for the jury your educational background.
A. Yes. I have a bachelor's in biology and chemistry from the University of Virginia.
Q. And so can you tell us how you got into the medical device industry?
A. Yes. I -- as a student, I was really interested in

medicine and always thought I was going to medical school. But as a student, I started working in clinical research and found that I really liked that side and could still be part of bringing products to patients but on the industry side instead of as a physician.

Q. When you were at Bard from 2003 to 2007, did you work on regulatory filings that relate to the Recovery filter and the G2 filter?

A. Yes, I did.

Q. And how -- just in general -- often do you think that you were in contact with the FDA during that time period?

A. I was in contact with them very frequently. At least on an every week, two weeks. It was a very frequent basis.

Q. And in your position, did you work on the 510(k) submissions for the Recovery and the G2 filters?

A. Yes, I did.

Q. And can you describe for us the types of submissions that they would have been?

A. Yes. We had 510(k) submissions and also IDE submissions, and that's investigational device exemption. Those are for conducting clinical studies.

Q. And in your experience in the regulatory industry, with a 510(k) submission, does the FDA usually require those to be accompanied by clinical data?

A. Generally, they do not. It's actually very uncommon with a

510(k) device to need to do a clinical study.
Q. And can the FDA, if they want, request clinical data?
A. Yes, they can.
Q. And can you tell us, when we are saying clinical data, what does that mean?
A. What that means is they will ask you to conduct a clinical study and collect information about the product, the use related to the safety and the effectiveness of the device in patients before the FDA will grant you approval to market the device.
Q. And based on your experience, why is it that in most 510(k) submissions, the FDA does not require clinical studies?
A. FDA generally doesn't because the -- when a 510(k) is cleared, it's based upon substantial equivalence to a currently marketed product. So generally they don't require clinical data, but in some cases they can ask for it.
Q. And do complex devices go through the 510(k) process?
A. Sometimes they do. There are cases where -- like vena cava filters or certain products where they're very complex. They could be orthopedic implants, lasers. A number of complex devices can still go through the 510(k) process.
Q. When you were submitting a 510(k) application to FDA, does FDA require nonclinical testing or bench testing?
A. Yes, they do. In most all cases, they'll require the bench and animal testing.

Q. You anticipated my next question. So FDA --
A. Sorry.
Q. That's all right.
So FDA also requires animal testing for 510(k) applications?
A. Yes. Many times they do.
Q. And in your experience in the regulatory field, if the FDA has got questions about a 510(k) application or another submission, does FDA follow up with the manufacturer that submitted the application?
A. Yes, they do. And it's not uncommon for them to follow up and ask questions about the submission.
Q. And did that occur with Bard's IVC filters?
A. Yes, it did.
MR. ROGERS: All right, Scott. Can you pull up Exhibit 5349, please.
BY MR. ROGERS:
Q. And can you see that on your screen?
A. Yes, I can.
Q. And can you describe just generally what that is.
A. This is a special 510(k) submission for the Recovery filter.
MR. ROGERS: Your Honor, I would move this into evidence.
MR. O'CONNOR: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit No. 5349 admitted into evidence.)

MR. ROGERS: Your Honor, just a question. Do you want us to go on the morning break now or --

THE COURT: We'll do it in four minutes.

MR. ROGERS: Okay. Thank you.

And may we display, please?

THE COURT: You may.

BY MR. ROGERS:

Q. And, Ms. Allen, you just described this -- I called you Ms. Allen. I'm sorry. You're Ms. O'Quinn. I apologize.

You just described this as a special 510(k) application; is that right?

A. Yes.

Q. And can you describe for the jury what that means.

A. A special 510(k) is a submission when you already have a similar product on the market, and there are established standards that you can claim compliance with to be able to get a quicker review time of the 510(k).

Q. And is this one of the submissions that you worked on personally?

A. Yes, it is.

Q. Can we go to page 4 of the document, please.

And is that the cover page for the 510(k) application?

A. Yes, it is.

Q. And can we go to page 6, please.

And what are we seeing here?

A. This is the Table of Contents of the 510(k).

Q. And so what types of things need to be included in a 510(k) application?

A. In a 510(k), it's generally a detailed description of the device, the changes that you're making, detailed summaries of all of the bench or engineering testing, the animal testing, and then if there is clinical data, it would be included as well.

MR. ROGERS: All right. Can we go to page 20, please.

And can you pull out Part B there, below there? Yeah, where it says Subject Device Description. Thank you.

BY MR. ROGERS:

Q. And tell us what we're seeing here, please.

A. This is a description of the device and the types -- a general summary of the type of modifications that were made to the device.

Q. And is that something that's always included in a 510(k) application?

A. Yes.

MR. ROGERS: All right. Thank you. We can take that down.

Can you pull up Exhibit 5905, please.

And, Your Honor, I move this into evidence.

MR. O'CONNOR: One moment, Your Honor.
MR. LOPEZ: Can we see all the pages, please?
MR. ROGERS: Sure.
MR. O'CONNOR: No objection.
Thank you for showing us those pages.
THE COURT: Admitted.
(Exhibit No. 5905 admitted into evidence.)
MR. ROGERS: May we display?
THE COURT: You may.
BY MR. ROGERS:
Q. Ms. Allen, we can see that this is an agenda. And can you tell us what this document is, what's it an agenda for?
A. Yes. This is an agenda for a meeting that we had between Bard and the FDA.
Q. And was this meeting held before or after you submitted the application, the special 510(k) for the G2 filter?
A. It was shortly after, within a few weeks.
Q. All right. And --
THE COURT: All right. We're going to break at this point, Mr. Rogers.
We will resume at 10 minutes to the hour. We'll excuse the jury at this time.
(Recess taken, 10:34 a.m. to 10:52 a.m.)
THE COURT: You may continue, Mr. Rogers.
MR. ROGERS: Thank you, Your Honor.

Scott, can we get back Exhibit 5905, please.

And, Your Honor, may we display?

THE COURT: You may.

BY MR. ROGERS:

Q. All right, Ms. Allen. Before we took the morning break -- I called you Ms. Allen again. I apologize.

Mrs. O'Quinn. Before we took the morning break, we were talking about this agenda. And can you tell us who prepared this agenda?

A. Yes. I prepared the agenda.

Q. And before we get into the specifics of it, can you tell the jury generally, how did this meeting with FDA come about?

A. Yes. After we filed the initial 510(k) application, it was for a permanent filter. And FDA asked us to do a clinical study for the retrievable indication. And so we wanted to have a meeting with the FDA to discuss the transition of the application and talk about the changes to make sure that they understood the nature of the changes before filing as a permanent indication only.

Q. And from looking at the agenda, who besides yourself from C.R. Bard was there?

A. Yes. Rob Carr was there. He was a lead engineer. Dr. Ciavarella was our medical officer. And then we brought a couple of physicians, Dr. Venbrux and Kaufman, with us as well to the meeting.

Q. And Drs. Venbrux and Kaufman, were they Bard employees?
A. No, they were not. They're physicians that use filters and have been involved in the various medical societies as advisers on vena cava filters.

MR. ROGERS: All right. Can you go to the next page, please.

BY MR. ROGERS:

Q. And so without -- we don't need to go over the names, but can you describe generally who from FDA was participating in this meeting?
A. Yes. There were a lot of FDA participants, probably 10 to 12 people from the office of the device evaluation, the people that review the 510(k)s, as well as people from the post-market surveillance that look at monitoring of these products once they're on the market.

MR. ROGERS: All right. And can you go back to the first page, please.

BY MR. ROGERS:

Q. And so, again, in broad strokes, what were the things that were discussed at this meeting?

MR. O'CONNOR: Objection. Hearsay.

THE COURT: Well, there's no call for specific testimony, but let's keep it general, to topics, before you ask any specific question that Mr. O'Connor might want to object to.

MR. ROGERS: Thank you, Your Honor.

THE WITNESS: Yeah. We wanted to share with them the nature of the changes that we were making to the device that were the subject of the 510(k). We also wanted to talk about some of our data collection initiatives and then what were the next steps in the 510(k) process.

BY MR. ROGERS:

Q. What was the outcome of the meeting?

A. The outcome of the meeting was that we agreed with FDA that we would submit a 510(k) for the permanent indication and conduct a clinical study for the retrievable indication.

Q. Okay. Thank you.

MR. ROGERS: Can we take that down, please, Scott?

And can you pull up Exhibit 5348.

BY MR. ROGERS:

Q. Ms. Allen, can you see this?

A. Yes, I can.

Q. And can you tell us just generally what it is?

A. It's a letter from the FDA, and they're -- they said they had reviewed our 510(k), and then to complete the review, they had some questions that they wanted us to respond to.

MR. ROGERS: Your Honor, I'd move this into evidence.

MR. O'CONNOR: Objection, Your Honor. Within this document there is hearsay within hearsay.

THE COURT: Any response, Mr. Rogers?

MR. ROGERS: Well, Your Honor, I don't know specifically what Mr. O'Connor is referring to. But, I mean, if there are specific things that he objects to that he feels like need to be redacted, we can certainly discuss that and come to some conclusion about it.

THE COURT: Mr. O'Connor, are you content to discuss that later, or is there something you're particularly thinking we need to address now?

MR. O'CONNOR: I'm told that we can discuss this later, but if it gets into that, I will remind everybody of that objection.

THE COURT: All right. So I will admit 5348 subject to redaction.

MR. O'CONNOR: Thank you.

(Exhibit No. 5348 admitted into evidence.)

MR. ROGERS: And may we display, or will that be an issue?

MR. O'CONNOR: You may display that first page.

MR. ROGERS: Okay. Thank you.

BY MR. ROGERS:

Q. Now, Ms. Allen, I think you were telling us that FDA had some questions; is that right?

A. Yes, that's correct.

Q. And can you tell us the types of questions that FDA was asking?

A. They were asking about the animal study that was conducted and included in the 510(k) and also questions about the instructions for use.
Q. And did the FDA also ask questions about a proof of concept study?
A. Yes, they did.
Q. And what would that be?
A. A proof of concept study is something like in this situation where there's a similar product on the market and we're collecting evidence for substantial equivalence. And we would conduct a study for the retrievable indication. That's what FDA was referring to as a proof of concept study.
Q. And did that ultimately lead to the EVEREST study?
A. Yes, that was the EVEREST study.
Q. Okay. And did FDA allow Bard to seek clearance of the G2 filter as a permanent device?
A. Yes, they did.
Q. And what did Bard do after FDA requested that the G2 be cleared as a permanent filter only?
A. We submitted the 510(k), and it was ultimately cleared by FDA for the permanent indication. And concurrently we conducted the proof of concept study for the retrievable indication.
MR. ROGERS: All right. We can take this down, please.

And can you pull up Exhibit 5350, please.
BY MR. ROGERS:
Q. And can you tell us what this document is?
A. This is a response to questions from the FDA on the 510(k).
Q. Thank you.
MR. ROGERS: And, Your Honor, I move this into evidence.
THE COURT: Is this 5350?
MR. ROGERS: Yes, sir.
THE COURT: All right.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit No. 5350 admitted into evidence.)
MR. ROGERS: May we display?
THE COURT: You may.
BY MR. ROGERS:
Q. All right. So very briefly, can you tell us again what this is?
A. Yes. It's a response to questions from the FDA on the Recovery filter 510(k).
MR. ROGERS: And, Scott, would you mind going to the next page? And then the following page. And the following page. Sorry about that.
BY MR. ROGERS:
Q. All right. So were you the person that signed this letter

to FDA?
A. Yes, I am.
Q. Okay. And so let's go back up to the second paragraph.
And so what are the types of things that Bard told FDA in response to its questions?
A. We supplied the information that they requested, and we also -- the excerpt here is showing that we converted from the traditional -- I apologize, from the special 510(k) to the traditional 510(k).
Q. All right. Can we go to page 17, please.
And so what is this that we're seeing?
A. This is the cover page for the traditional 510(k) submission.
Q. All right. And can we go to page 91, please.
And what is this?
A. This is the cover page for a protocol for the design verification and validation testing. That's the engineering testing that was conducted to support the filter.
Q. And was that provided to FDA?
A. Yes.
Q. All right. And can we go to page 127.
And what is this?
A. This one is the cover page for the actual report. The previous one was the protocol, and this is the report.
Q. And was that provided to FDA?

A. Yes, it was.
Q. All right. And can we go to page 148.
And what do we see here?
A. This is the report for the animal study.
Q. All right. And was that submitted to FDA as part of this application?
A. Yes.
Q. And is that the report or the protocol?
A. It says a protocol, but when I saw the "TPR," I thought that meant report, so I would need to verify if it's the protocol or the report. But they were both provided to FDA.
Q. All right. Well, let's go to page 158.
And does that indicate that that was the test report?
A. No. This is the protocol signature page.
Q. Okay. Excuse me.
All right. Let's go to page 184.
And what is this?
A. This one is the actual test report for the animal study.
Q. And was that submitted to FDA?
A. Yes.
MR. ROGERS: All right. You can take that down, please.
And can you pull up Exhibit 5344.
Your Honor, I move this into evidence.
MR. O'CONNOR: One moment, Your Honor. We have a note

on some of these, please.

Can we just scroll through the pages real quickly, please?

No objection.

THE COURT: Admitted.

(Exhibit No. 5344 admitted into evidence.)

MR. ROGERS: May we display?

THE COURT: Yes.

BY MR. ROGERS:

Q. All right. So what is this, please?

A. This is a letter from the 510(k) regarding -- I'm sorry, a letter from the FDA regarding the 510(k). And they were asking some questions.

Q. And so were these additional questions that FDA had based on the application that was submitted?

A. Yes.

Q. And is it typical for FDA to send follow-up letters like this asking questions about a 510(k) application?

A. Yes, it is.

Q. All right. And if we look on the first page there, just to give the jury some idea, what were the types of questions that -- in that first paragraph?

MR. ROGERS: Can you pull that out, please?

BY MR. ROGERS:

Q. What were the types of things that the FDA wanted to know

about the animal data?
A. Yes. Because FDA had some questions about the animal data regarding the retrievability of the filter, they asked for additional information related to a rationale for why the animal study was still applicable to the filter as a permanent filter.
Q. All right. Thank you.
MR. ROGERS: And can you take that down? And let's pull up paragraph 2.
BY MR. ROGERS:
Q. And what was the FDA asking here?
A. In this paragraph, the FDA wanted us to ultimately -- well, ultimately, we changed the name of the filter to address their concern, because their concern was that the name of the filter as "Recovery" filter suggested that it could be recovered or retrieved. So they asked us to address that concern, and our response was that we would change the name to avoid any suggestion that it was a retrievable filter.
MR. ROGERS: All right. Can you take that down, please?
And let's go to Exhibit 5352.
BY MR. ROGERS:
Q. And did Bard ultimately respond to FDA's questions?
A. Yes. This is the cover page for our response.
MR. ROGERS: And, Your Honor, we move this into

evidence.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit No. 5352 admitted into evidence.)

MR. ROGERS: May we display?

THE COURT: Yes.

BY MR. ROGERS:

Q. And again, in just generalities, what did you tell FDA in response to their questions?

A. Yes. We -- as I mentioned, we changed the name of the filter on all of our labeling and documentation to change to G2 to avoid implication that it was a retrievable filter. And then we provided rationales to address their questions about the animal testing.

Q. And did FDA ultimately clear this application for the G2 filter as a permanent filter?

A. Yes, they did.

MR. ROGERS: All right. Can we pull up Exhibit 5343.

BY MR. ROGERS:

Q. And is this the clearance letter?

MR. O'CONNOR: No objection.

THE COURT: He hasn't moved it yet, but thank you, Mr. O'Connor.

MR. ROGERS: Yeah, thank you.

Your Honor, may I move this into evidence?

THE COURT: He hasn't moved it into evidence yet, but thank you for not objecting.

MR. O'CONNOR: Oh, I apologize.

THE COURT: That's all right.

Did you want an answer to the question?

THE WITNESS: Do you want me to answer?

MR. ROGERS: Well, let's go ahead and move it into evidence since we're already there.

THE COURT: All right. 5343 is admitted.

(Exhibit No. 5343 admitted into evidence.)

MR. ROGERS: May we display?

THE COURT: Yes.

MR. O'CONNOR: I was just predicting.

BY MR. ROGERS:

Q. All right. So did FDA clear the device?

A. Yes, they did.

Q. And is this the clearance letter from FDA?

A. Yes, it is.

Q. All right. Thank you.

MR. ROGERS: You can take that down.

BY MR. ROGERS:

Q. So in addition to the clearance of the G2 as a permanent device, were you involved in any other clearance processes with the FDA that related to the G2?

A. Yes. I was involved in a couple of additional 510(k)s

while I was there related to delivery system changes.

MR. ROGERS: All right. Can we pull up Exhibit 5354.

And, Your Honor, I move this into evidence.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit No. 5354 admitted into evidence.)

MR. ROGERS: May we display?

THE COURT: Yes.

BY MR. ROGERS:

Q. All right. So what is the purpose of this 510(k) submission?

A. This was a special 510(k) for the jugular delivery system.

Q. And did FDA clear the jugular delivery system for the G2?

A. Yes, they did.

MR. ROGERS: All right. So can you take that down, please, and pull up 5353.

And, Your Honor, I move this into evidence.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit No. 5353 admitted into evidence.)

MR. ROGERS: May we display?

THE COURT: Yes.

BY MR. ROGERS:

Q. And is this the clearance letter for the jugular delivery system?

A. Yes, it is.

MR. ROGERS: All right. So can you take that down, please, and pull up Exhibit 5361.

BY MR. ROGERS:

Q. And can you tell me generally what this is?

A. This is the cover letter for the special 510(k) submission for the femoral delivery system.

MR. ROGERS: And, Your Honor, we move this into evidence.

MR. O'CONNOR: Your Honor, as I understand, there are parts of this document that need to be redacted.

THE COURT: All right. Do you intend to show any portion of it now, Mr. --

MR. ROGERS: Your Honor, I'll just keep it to the cover page.

THE COURT: All right. Any objection to admitting it subject to redaction?

MR. O'CONNOR: No, not subject to redaction.

THE COURT: All right. It's admitted subject to redaction.

(Exhibit No. 5361 admitted into evidence.)

MR. ROGERS: May we display?

THE COURT: Yes.

BY MR. ROGERS:

Q. All right. So can you tell us what we're looking at here?

A. Yes. This is the cover page for the special 510(k) for the femoral delivery system.
Q. And what was the purpose of this submission?
A. This one was to make a modification to the delivery system. The specific changes to the femoral, I would need to see the description in order to recall the specific changes.
MR. ROGERS: Well, why don't we take that down and instead pull up Exhibit 5362.
BY MR. ROGERS:
Q. And can you tell us what this document is?
A. Yes. This is the letter from the FDA granting clearance for the 510(k).
MR. ROGERS: Your Honor, we move this into evidence.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit No. 5362 admitted into evidence.)
MR. ROGERS: May we display?
THE COURT: Yes.
BY MR. ROGERS:
Q. And I know you've already said this, but is this the letter clearing the delivery system for the femoral delivery?
A. Yes, it is.
Q. All right. Let me kind of change gears on you.
MR. ROGERS: And you can take that down, please.

BY MR. ROGERS:

Q. And I want to talk to you a little bit about the EVEREST clinical trial, which we mentioned earlier. And can you remind the jury what that trial was?

A. Yes. That was the clinical study that we agreed to conduct with the FDA that we've referred to as the proof of concept study. But it was a clinical study that we conducted on the retrievable indication, and that was the evidence that was needed, the clinical evidence that was needed in order to get the retrievable indication.

Q. And you have worked in the medical device industry for 20 years or so; correct?

A. Yes, that's correct.

Q. And in your experience, have you worked on various medical devices that have been cleared through the 510(k) process?

A. Yes, I have.

Q. And is that for a number of different companies?

A. Yes, a number of different companies.

Q. And how often does the FDA require clinical studies to be conducted with the 510(k) application?

A. It's actually very rare. There aren't many that are conducted for the 510(k)s.

Q. And do you know when the EVEREST study started?

A. I don't know exactly. I think around 2005.

Q. And was the G2 filter available to physicians with the

permanent indications on the market before the EVEREST study started?
A. Yes, it was.
Q. And in your experience, is there anything unusual about this process for the G2 filter compared to other IVC filters?
A. Nothing unusual, no.
MR. ROGERS: All right. Can we pull up Exhibit 5324, please.
BY MR. ROGERS:
Q. And can you tell us what this document is?
A. This is the IDE application. This is the cover letter for that IDE, which is a request to conduct a clinical study.
MR. ROGERS: Your Honor, I move this into evidence.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit No. 5324 admitted into evidence.)
MR. ROGERS: May we display?
THE COURT: Yes.
BY MR. ROGERS:
Q. All right. Now, you mentioned a moment ago that this was something called an investigational device exemption.
A. Yes.
Q. Can you explain to the jury what that is?
A. Yes. An IDE is -- it's similar to a 510(k) in terms of the type of information you include regarding the description of

the device, a risk analysis of the device of the type of risks that might occur during the study. Also, extensive engineering, bench testing and animal testing, that's provided along with a protocol for conducting the clinical study.

MR. ROGERS: All right. Can we go to page 13 of the document?

BY MR. ROGERS:

Q. And is this the Table of Contents for the IDE application?

A. Yes, it is.

Q. And can you describe for us generally, just what are the things that you submitted here?

A. Yeah. Here we have the risk and benefit analysis, the objectives of the study, the endpoints, the overall design, the eligibility criteria that the patients need to meet in order to be qualified to participate in the study, the type of procedures and screening that the patients will receive during the trial, and then detailed information about the adverse events that we will observe and collect and how we will report those.

MR. ROGERS: All right. Let's go to page 57.

And can you pull out Section E, please, the bottom.

BY MR. ROGERS:

Q. What is this?

A. This is a general description of the design of the study.

Q. All right. And in that last sentence there, do you see

where it says: All patients enrolled in the study will be followed to six months post filter replacement or to one month post filter retrieval, whichever comes first?
A. Yes.
Q. And why was that given to FDA as a parameter of the study?
A. That is a typical time frame for a clinical study. So what you want to do is look at a duration of the study that's long enough to observe if the product is safe, is it effective for its intended use; and six months is actually a very reasonable time frame for studies, even in cardiovascular trials. They can be six months.

And then one month after the filter was retrieved, if it was retrieved.
Q. Was it ever Bard's intention that if the G2 filters in the EVEREST study were not retrieved within six months, that the filter had to be a permanent filter?
A. No.
Q. And whose discretion was it up to in order to determine when those filters should be retrieved?
A. It's the physician's discretion of when they could be retrieved. It just -- for the purposes of a study, you need to define what is the endpoint of the study. But those patients would continue to be followed by their physicians, and the physicians would make the determination of when the product should be retrieved, or it could remain a permanent filter.

MR. ROGERS: Okay. Can we back up a couple of pages to 55, please? And can you pull out Section B?

BY MR. ROGERS:

Q. And can you tell us what this is, please?

A. This is a summary of the benefit and risk analysis.

Q. And is that a typical portion of an IDE application?

A. Yes. That's a standard requirement for an IDE application is that you need to include a summary of the benefits as well as the potential risks that the patients might experience while participating in a study.

Q. And so as part of that, did Bard inform FDA about potential complications that may occur with patients in the study?

A. Yes.

Q. And did Bard inform FDA that fracture was a potential complication of the study?

A. Yes.

Q. Did Bard tell FDA that migration was a potential complication in the study?

A. Yes.

Q. Did Bard tell FDA that perforation was a potential complication in the study?

A. Yes.

MR. ROGERS: All right. Can we go to page 57, please. And can we pull out the section that's Part D.

BY MR. ROGERS:

Q. We see that this section is called Study Endpoints. Can you tell us what those are?

A. Yes. As a part of a clinical study, you need to determine what are the primary endpoints of the study, and that is what determines if the study is a success or not. It doesn't mean that you won't collect additional information, but those are the primary endpoints of the study.

MR. ROGERS: All right. And number 3, can you pull that out, please, Scott?

BY MR. ROGERS:

Q. It reads: Adverse events occurring at the time of retrieval through 30 days post filter retrieval procedure.

What does that mean?

A. Yes. That means that we will collect information on any of the adverse events that occur during this study, and that's regardless of whether they're related to the device or not. We'll collect all adverse events.

Q. And if the EVEREST study is described as a retrievability study, is that a correct description?

A. We also, because the filters also could be used as a permanent, we looked at indications that were relevant to both the permanent and the retrievable indication.

Q. And would it be correct to say that the issues of safety were not looked at during this study?

A. Could you repeat that?
Q. Sure. Would it be correct to say that this study did not look at issues of safety?
A. No. It very much did look at safety.
MR. ROGERS: All right. Let's go to page 54, please.
And if you would, go up to the top where it says Filter Migration, the second one, and pull that out. Thank you.
BY MR. ROGERS:
Q. And do you see that?
A. Yes.
Q. All right. And if you just read along with me, I'd appreciate it.
But it says: A change in filter position compared to its deployed position (either cranial or caudal) of more than 2 centimeters as documented by plain film imaging, CT, or venography.
Did I read that correctly?
A. Yes.
Q. And was this the definition of migration that was used in the study?
A. Yes, it is.
Q. And why was that definition of more than 2 centimeters, why was that used as the definition for migration?
A. That definition was something that we had extensive

discussions with the FDA, and that was an industry standard definition that was used. Because any movement less than 2 centimeters is difficult to detect.

Q. All right. Did FDA send Bard a letter asking questions about this definition?

A. Yes. We had a lot of discussion with FDA about how -- why that definition is relevant.

MR. ROGERS: All right. Can we take that down and pull up Exhibit 5323.

BY MR. ROGERS:

Q. And is this the letter that FDA sent asking questions about the migration definition for the EVEREST study?

A. Can I see the second --

Q. Yeah, you need to go to the second page.

Do you see number 4?

A. Yes. There it is, yeah. It's on number 4.

MR. ROGERS: Okay. Your Honor, I move this into evidence.

MR. O'CONNOR: No objection.

THE COURT: 5323 is admitted.

(Exhibit No. 5323 admitted into evidence.)

MR. ROGERS: May we display?

THE COURT: Yes.

BY MR. ROGERS:

Q. All right. So this is the letter that FDA sent asking some

specific questions about the EVEREST study?
A. Yes.
MR. ROGERS: All right. And can we pull out number 4, please.
BY MR. ROGERS:
Q. And what did FDA ask in this particular question?
A. FDA was asking questions about the 2 centimeters, and asked us to either revise the definition or to provide information on why 2 centimeters is the appropriate definition.
Q. All right. And did FDA ultimately respond to this question?
A. Yes, they did.
Q. And did the FDA grant Bard conditional approval to start the EVEREST study?
A. Yes.
MR. ROGERS: All right. Can we pull up Exhibit 5325, please.
BY MR. ROGERS:
Q. And can you tell me what this is, please?
A. This is our response to FDA's questions about the IDE.
MR. ROGERS: Your Honor, I move this into evidence.
MR. O'CONNOR: I believe that this document has hearsay, Your Honor, which we objected to. So I think that we would agree to admission subject to redactions of hearsay.
THE COURT: All right. Admitted subject to redaction.

(Exhibit No. 5325 admitted into evidence.)

MR. ROGERS: Your Honor, may I ask a follow-up question?

I'd like to display the response to Question 4, and I don't know if there's anything objectionable in that particular portion.

MR. O'CONNOR: Can we see it, please?

Yeah. Your Honor, we would object as hearsay.

THE COURT: All right. Let's talk about that for just a minute, counsel.

If you want to stand up, ladies and gentlemen, feel free.

(At sidebar on the record.)

THE COURT: What's your response, Mr. Rogers?

MR. ROGERS: I'm assuming the objection is where it says "FDA accepted." Is that the issue?

MS. SMITH: Yeah. It's summarizing the FDA's response.

THE COURT: It says FDA accepted the 2 centimeter --

MR. ROGERS: Correct.

THE COURT: -- subject to collecting additional data on any movement.

MR. ROGERS: Yes, Your Honor. Right.

THE COURT: Why is that not a reflection of what FDA said in the meeting or in the phone call that it's referring

to?

MR. ROGERS: Well, Your Honor, I think it goes to what occurred and as far as what Bard's state of mind was in response to this meeting.

THE COURT: Well, but it's being offered to say that FDA accepted the 2-centimeter definition. Right?

MR. ROGERS: Okay. I would agree with you.

THE COURT: Okay. That's the truth of what the FDA said in the meeting. Well, the conference call.

MR. ROGERS: Okay. We won't go into it, then.

THE COURT: All right. So you're not going to display that part?

MR. ROGERS: No, sir.

THE COURT: So that is still subject to redaction in evidence, but we won't talk about that part.

MR. ROGERS: Okay. Thank you.

MR. O'CONNOR: Thank you.

(End of discussion at sidebar.)

THE COURT: Thank you.

BY MR. ROGERS:

Q. All right. Did Bard proceed with the EVEREST study with a definition of migration of 2 centimeters?

A. Yes, we did.

Q. And did the FDA ultimately clear the IDE application?

A. Yes, they did.

Q. And did the FDA clear the IDE application with the definition of migration as 2 centimeters?
A. Yes.
MR. ROGERS: All right. Can we go to page 79, please. That's not very helpful.
How about page 80. That's not very helpful either.
Okay. Let's just kind of move along then.
BY MR. ROGERS:
Q. Let me ask you a question. What is a secondary endpoint for a clinical study?
A. A secondary endpoint is something that is important to collect within the study and to report on that, and that helps FDA make the determination of does -- is the device safe and effective for its use. And the secondary endpoints are not the primary ones that are used to determine the success of the study, but they're endpoints that you specifically report on because FDA feels that those are important endpoints.
Q. And in the EVEREST study, was the adverse event data a secondary endpoint?
MR. CONDO: Your Honor --
MR. ROGERS: Oh, sorry, Your Honor. We have a --
JURY MEMBER: I'm beeping.
THE COURT: All right. Hold on just a second.
Is that working?
JURY MEMBER: Yes. Thank you.

THE COURT: Okay. You may proceed, Mr. Rogers.

BY MR. ROGERS:

Q. In the EVEREST study, was adverse event data considered a secondary endpoint?

A. I believe it was considered a secondary endpoint. I could verify in the protocol, but my recollection is that it was.

MR. ROGERS: Okay. Can we pull up Exhibit 5322.

BY MR. ROGERS:

Q. And can you tell me what that is, please?

A. Yes. This is the letter from the FDA approving the IDE.

MR. ROGERS: Your Honor, I move this into evidence.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit No. 5322 admitted into evidence.)

MR. ROGERS: May we display?

THE COURT: You may.

BY MR. ROGERS:

Q. And again, very briefly, is this the letter where they cleared the IDE?

A. Yes.

MR. ROGERS: What's the -- and you can take that down, Scott. Thank you.

BY MR. ROGERS:

Q. What's the -- the IDE was cleared, and Bard started the process of the EVEREST study. Did Bard provide FDA with

updates on the progress of the study?
A. Yes, we did.
Q. And what is the purpose of doing that?
A. The purpose of that is to keep FDA informed of the progress of the study and any adverse events or safety information that we're observing during the study.
MR. ROGERS: Can we pull up Exhibit 5333.
BY MR. ROGERS:
Q. And can you tell me what this is, please?
A. Yes. This is called an annual progress report, and this is a report that was submitted to the FDA reporting on the progress of the IDE.
MR. ROGERS: Your Honor, I move this into evidence.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit No. 5333 admitted into evidence.)
MR. ROGERS: May we display?
THE COURT: Yes.
MR. ROGERS: All right. Can we go to pages 33 and 34, please.
BY MR. ROGERS:
Q. And down at the bottom of page 33, where it says "Summary of Anticipated and Unanticipated Adverse Events," do you see that?
A. Yes.

Q. And can you tell me what this is?
A. This is part of the annual progress report, and this specific excerpt talks about the reporting of adverse events during the study and that we utilized it -- utilized an independent physician who was acting as the medical monitor for the study, and his role is to ensure an unbiased assessment of adverse events that occur during the study.
MR. ROGERS: All right. Can you take out the -- take down the box, please.
And then looking -- and on the next page, on page 34, can you pull out that first full paragraph? Well, the one below that.
BY MR. ROGERS:
Q. Okay. Can you see that?
A. Yes.
Q. And can you tell us here what sort of information Bard is providing to FDA in this paragraph?
A. This is an update on the number of filter migrations that had occurred that were greater than the 2 centimeters. And it said that all four of them were in the caudal direction, and they were asymptomatic.
Q. And asymptomatic means that the patient experienced no symptoms?
A. Yes, that's correct.
MR. ROGERS: All right. Can we go to page 57, please.

And can you try to make that a little bigger?

BY MR. ROGERS:

Q. Okay. Can you tell us what we're seeing here?

A. Yes. This is a listing of the adverse events that occurred during this study.

Q. And did Bard provide these in these reports to FDA about the EVEREST study?

A. Yes.

Q. And so if the -- were the events reported, did they necessarily have something to do with the filter?

A. No, they didn't. As you can see, in some cases it was pneumonia or dehydration. We collected all adverse event information, not just that related to the device.

Q. And so if any adverse event occurred during the course of the EVEREST study that really related to anything, did that have to be reported to FDA?

A. Yes.

MR. ROGERS: All right. You can take that down.

BY MR. ROGERS:

Q. And I want to talk to you a little bit more about caudal migration.

And were you familiar, when you were at C.R. Bard, with reports of caudal migration with the G2 filter?

A. Yes.

Q. And what is your understanding in the device industry

regarding the potential severity of caudal migration?

MR. O'CONNOR: Objection. Calls for expert opinion.

THE COURT: Hold on just a minute.

Overruled.

THE WITNESS: So I can answer?

BY MR. ROGERS:

Q. Sure, you can.

A. Okay. I'm sorry. I forgot the question now.

Q. That's all right.

MR. ROGERS: Would you mind reading the question back?

(Record read.)

THE WITNESS: Yes. For caudal migration, the belief is that those are generally asymptomatic, meaning that there's no clinical symptoms associated with them.

BY MR. ROGERS:

Q. And what did Bard do when it started to receive reports about G2 caudal migration?

A. We convened a panel of physicians to get input from expert physicians, and we discussed it also with the FDA.

Q. And did you work on the team of people who were investigating the caudal migrations?

A. Yes.

Q. And, you know, the jury has heard that in 2006 the complaint rate for G2 caudal migration exceeded what is known as the DFMEA rate.

Do you understand what I'm saying there?
A. Yes.
Q. And did Bard undertake an investigation of that?
A. Yes.
Q. And were you part of that?
A. Yes.
Q. And, in general, what actions did the company take when they learned or when you learned that DFMEA rate of caudal migration or migration was exceeded?
A. Yeah. We set those at conservative rates in order to trigger us to take action to start an investigation. And as part of that investigation, we did extensive evaluation of our -- the clinical experience, the engineering, testing. We talked to physicians, to FDA, to try to get as much information as possible to understand the caudal migrations.
MR. ROGERS: And can we pull up Exhibit 5881, please.
BY MR. ROGERS:
Q. And can you tell me what this is?
A. This is a letter from -- let's see, sorry -- this is a --
Q. Do you want to go to the second page?
A. Yeah. Let me see the second page.
Okay. Yeah, this is a response from Bard to the FDA regarding a --
MR. O'CONNOR: Objection, Your Honor.
THE WITNESS: -- it's called a MedWatch report.

THE COURT: Hold on. Hold on just a minute, please.

What?

MR. O'CONNOR: She's reading from the document. The document's hearsay, and I'm objecting on 602.

THE COURT: Well, I don't think she was reading. She was describing it.

But you're objecting to any reference to the document on what basis?

MR. O'CONNOR: Yes. Based upon hearsay at this point.

THE COURT: Hearsay?

MR. O'CONNOR: And 602.

THE COURT: All right. What's your response on 602?

MR. ROGERS: 602, Your Honor, I'll be glad to lay the foundation.

THE COURT: Okay.

MR. ROGERS: And as far as hearsay, I think this is a business record.

THE COURT: All right. What's your response on business record, Mr. O'Connor?

MR. O'CONNOR: Well, Your Honor, it looks as though there are statements in here that were done by people other than -- with expertise other than this witness. And I'm specifically looking under paragraph 4 and 3, so that would be 602 and that would still be hearsay.

THE COURT: What's your response on business record?

Which is Mr. Rogers' response to your hearsay objection.

MR. O'CONNOR: Foundation at the present time.

THE COURT: All right. I think you need to lay foundation on both.

MR. ROGERS: I'll be glad to, Your Honor.

BY MR. ROGERS:

Q. Ms. Allen -- or Ms. O'Quinn, excuse me, when you were working at C.R. Bard, did you work on this particular letter?

A. Yes, I did.

Q. And was this part of the team's response that was looking into caudal migration?

A. Yes.

Q. And if we look at the signature of the person who signed the letter, who is that?

A. That's Cindy Walcott.

Q. And did you work directly with Ms. Walcott in the preparation of this letter?

A. Yes.

MR. ROGERS: Your Honor, I move this into evidence.

THE COURT: Well, that addresses the foundation but not the business record issue.

BY MR. ROGERS:

Q. Ms. Allen -- or Ms. O'Quinn -- I'm going to do that every single time, so I apologize.

A. That's okay.

Q. Is this a document that Bard would have kept in the ordinary course of business?
A. Yes.
Q. And would it have been written by people who were knowledgeable about its contents?
A. Yes.
Q. And was it Bard's usual practice to maintain this letter at Bard?
A. Yes.

MR. ROGERS: Your Honor, I move this into evidence.

THE COURT: Any further objection, Mr. O'Connor?

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit No. 5881 admitted into evidence.)

MR. ROGERS: May we display?

THE COURT: You may.

BY MR. ROGERS:
Q. All right. Now, you told us a little bit about Ms. Walcott, who signed this letter. What was her job?
A. Cindy's job was as part of our field assurance or our clinical assurance group, which monitored any of the events that occurred once a product was launched on the market.

And any of the correspondence that she had with FDA, either I or someone on my regulatory team would review that correspondence before it went to the FDA.

Q. And why would it be that this letter came from her as opposed to yourself or someone in the regulatory department?
A. And that's where originally I was looking at the title of it. It says Manufacturer Report Number, so Cindy's responsibility was whenever there were events that occurred that needed to be reported to the FDA, her group would do that, and there are numbers that are assigned to it.

So any of the correspondence regarding those specific manufacturer report numbers would come from Cindy or her team, with review and collaboration from our regulatory team.

MR. ROGERS: Okay. Can we pull out the response to Question 4, please.

BY MR. ROGERS:

Q. And what did Bard tell FDA about the caudal migration experience in EVEREST?

And that may have been a poorly worded question. Let me ask you again.

What did Bard tell FDA about the DFMEA rate being exceeded with the threshold that had been set for migration?
A. Yeah. In this part of the response, we said that it had been exceeded, but that we reassessed the DFMEA and the overall risk level and that it still remains at an acceptable level.
Q. And were you part of this team that worked on adjusting the level regarding caudal migration?
A. Yes.

Q. And is that something that the team did together?
A. Yes.
Q. And what were the reasons that the team decided that this threshold level should be changed for caudal migration?
A. Because originally the threshold was set based upon any kind of migration, either cephalad, towards the heart, or caudal, towards the feet.

And based upon the feedback that we received from physicians and others, the belief was that cephalad migration was generally asymptomatic, so we wanted to separate those and report them separately.

Q. And did FDA respond to this letter?
A. I recall that they did.

MR. ROGERS: Okay. Can we pull up Exhibit 5879, please.

BY MR. ROGERS:
Q. And can you identify this, please, for the record, what this is.

MR. ROGERS: And, Scott, do you mind showing both pages, please?

THE WITNESS: This was a clarification to that previous response, and it was clarifying the expected and the observed frequency and severity rates.

BY MR. ROGERS:
Q. And was the letter signed by Cindy Walcott again?

A. Yes.
Q. And did you work on the response to this letter?
A. Yes.
Q. And so do you have personal knowledge about the contents of this letter?
A. Yes.
Q. And was this letter kept by C.R. Bard in the regular course of business?
A. Yes.
Q. Was it written by people knowledgeable about the contents?
A. Yes.
Q. And is it maintained by C.R. Bard at C.R. Bard?
A. Yes.

MR. ROGERS: Your Honor, I move this into evidence.

MR. O'CONNOR: Objection, Your Honor. 602 and hearsay, especially including the tables that are on this document.

THE COURT: Well, I'm not understanding that. If you want to talk about it, perhaps we should do that at sidebar.

(At sidebar on the record.)

THE COURT: Explain your hearsay objection, Mr. O'Connor.

MR. O'CONNOR: Well, I'm specifically objecting to the reference in there on the SIR guidelines of being hearsay.

MS. SMITH: And her personal knowledge of the DFMEAs.

THE COURT: Well, the question is did she have knowledge of the creation of this letter. She's clearly said she does. He's laid the foundation for it being a business record and satisfied 803(6). So I'm not understanding --

MS. SMITH: I'd say the underlying data of this, if she's just going to read from the letter and she doesn't understand how that portion of it was put together. It comes from a completely different department. She likely copied and pasted into the letter without true knowledge of -- regulatory does not work with -- it's an engineering department.

THE COURT: Well, but if it's in a document that she has knowledge of, under 602 she can testify about it. If it's a business record, it's not hearsay. You're seeming to suggest they not only have to lay foundation that it's a business regard that she helped create --

MS. SMITH: Right.

THE COURT: -- but that when she created it, she had personal knowledge of specific items of fact that went into the letter. Is that the argument?

MS. SMITH: Yes, I think that she doesn't -- yeah, it is. That she doesn't have -- she did create the letter, and I think she can testify to the creation of the letter, but the hearsay within hearsay is that this is coming from an engineering department, and so when she put this in the letter, she doesn't -- at that point in time and, truly, today, she

does not have personal knowledge or data, the foundation to testify regarding those results.

Although she did create the letter, so she knows about that the letter was submitted and that they responded.

THE COURT: Well, it seems to me --

MS. SMITH: She can testify regarding that.

THE COURT: If your objection -- if he asks, explain to the jury what is in the DFMEA and how it was arrived at, that would be where you would object. Right?

MS. SMITH: Right.

THE COURT: You're saying that's what she doesn't know?

MS. SMITH: Correct. And I think he did that a little bit in his last question. He kind of piggybacked on: What did you provide the FDA? What did you tell them regarding this?

THE COURT: But that goes beyond the admissibility of the document, doesn't it?

MS. SMITH: Maybe. I don't know. Yes. Yes.

THE COURT: It seems to me what we're dealing with now is whether this is admissible as under the hearsay exception and whether she has personal knowledge of its creation sufficient to get it into evidence.

And I think she's testified she helped create it and it's a business record, so it comes in. It seems to me the objection you're raising is if he wants to drill down into

specific details of that information in the letter that she may not have personal knowledge of.

MS. SMITH: That's correct.

MR. O'CONNOR: That's right.

THE COURT: So the objection will be to a question on that point rather than to the admissibility of the document.

MS. SMITH: That is correct.

THE COURT: Okay. So you can make those objections if they arise, but I'm going to admit the document.

MR. LOPEZ: Your Honor, can I just -- I'm going to -- we probably should do this every time, but we want to renew our 403 motion on the fact that this letter's being written to someone we can't depose, we can't cross-examine, we can't do any discovery against.

There's no way for us to counter any of this evidence that goes to FDA because the people to whom it goes to, we cannot get the other side of the story. So I just want to again renew our 403 motion about these. It's just unfair for us to have to listen to this stuff that comes in and not have any ability to counter it.

THE COURT: And that would have to do with everything Bard submits to the FDA. Right? That you can't then go depose people at the FDA?

MR. LOPEZ: Just to see exactly whether they can confirm or not confirm what happened. We just get Bard's side

of the story.

THE COURT: Okay.

MR. ROGERS: And, Your Honor, for the record, I would like to respond that they did call a regulatory expert and they could have asked the expert questions regarding submissions to FDA and correspondence and what they think that her interpretation of that might be.

THE COURT: Well, that's all on the record. I'm not going to revisit that 403 ruling.

But while we're here, are you going to ask her to go into details of how the information in the table was derived?

MR. ROGERS: I was not planning on it, Your Honor. I really -- all I wanted to do was ask her what was conveyed to FDA.

THE COURT: All right. Thank you.

(End of discussion at sidebar.)

THE COURT: Thank you, ladies and gentlemen.

Exhibit 5879 is admitted.

(Exhibit No. 5879 admitted into evidence.)

MR. ROGERS: Your Honor, may we display?

THE COURT: You may.

BY MR. ROGERS:

Q. All right. Mrs. O'Quinn, we've talked about this, and can you again tell us what the purpose of this letter was?

A. Yes. This letter was a clarification to our previous

response where we wanted to provide clarification to Item No. 4.

Q. And what was conveyed to FDA in this clarification?

A. Is that although the threshold rates had been exceeded, that it was -- Bard had established these very low internal threshold rates in order to trigger monitoring to conduct an investigation. And we reported what those rates are, and we also provided the latest rates based upon our U.S. sales to date for the G2 filter.

MR. ROGERS: Okay. Thank you. You can take that document down.

And can we pull up Exhibit 5879, please.

Or, excuse me, that's what we just had. Sorry about that.

Exhibit 5880.

BY MR. ROGERS:

Q. And can you tell us what this document is?

A. And can I see the --

Q. Sure. Do you need to see the next page?

A. Yeah.

Okay.

Q. And generally, can you tell us what this is?

A. Yes. This is another instance where the FDA had asked for information about a specific medical device report, and Cindy Walcott, the clinical assurance person, was responding to that

request.
Q. And did you have personal knowledge of this letter when you were at C.R. Bard?
A. Yes.
Q. And did you help work on the response to this letter?
A. Yes.
Q. And you would have been involved in any clearance process before this letter was sent to the FDA?
A. Yes.
Q. Was this letter maintained at Bard in the ordinary course of business?
A. Yes.
MR. ROGERS: Your Honor, I move this letter into evidence.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit No. 5880 admitted into evidence.)
MR. ROGERS: May we display?
THE COURT: Yes.
BY MR. ROGERS:
Q. And if you would, can you explain to the jury why Bard sent this letter?
A. Yes. FDA had asked for additional information about that -- they're called MedWatch reports. And we were supplying that information. And we provided detailed information about

the current rates of migration for the filter, and again, shared information from the DFMEA on our threshold rates.

MR. ROGERS: And can we pull out the second paragraph on the second page?

BY MR. ROGERS:

Q. And what did Bard tell the FDA about exceeding the rates of migration in the DFMEA?

MR. O'CONNOR: Well, objection, Your Honor. 602, and I think the document speaks for itself.

THE COURT: Overruled.

THE WITNESS: So answer?

BY MR. ROGERS:

Q. You may respond.

A. Okay.

We said that although the observed frequency of the occurrence was higher than the threshold, that upon additional assessment of the DFMEA, which was our standard process when those thresholds were triggered, we reassessed the DFMEA and that the risk remained acceptable per our risk management process.

Q. All right. Thank you.

Moving to a little bit different subject matter, were you involved in something called a health hazard evaluation that was conducted regarding caudal migration?

A. Yes.

MR. ROGERS: And can we pull up Exhibit 1221, please.

And, Your Honor, I believe this is in evidence.

THE COURT: Yes.

MR. ROGERS: May we display?

THE COURT: You may.

BY MR. ROGERS:

Q. And so what was your role in this process?

A. My role in the process was that whenever a health hazard evaluation was being prepared, there was a cross-functional team of people that worked on this evaluation, and my role was to represent regulatory and clinical.

Q. And so what is the general purpose of this document that we're seeing?

A. The general purpose is to -- in this case, it was related to migration. It was to do a detailed evaluation of the risks related to migration.

MR. ROGERS: All right. And can you pull out the box that's at the top, please.

BY MR. ROGERS:

Q. And according to this summary, how many reports of migration had Bard received in regard to the G2 filter?

A. Bard had received ten reports: one cephalad and nine caudal migrations.

Q. All right. And looking down at the Conclusion section, do you know what the reporting frequency of migration for the G2

was at this time?
A. According to the HHE, it was 0.16 percent.
Q. And that would be the total migration number, both cephalad and cranial migration?
A. Yes.
Q. Excuse me, I misspoke.
That would be both types of migration, both cranial and caudal?
A. Yep.
Q. So the rate there is .16 percent; is that right?
A. Yes.
Q. And would that be the equivalent of, for every 1,000 G2 filters sold, there were approximately 1.6 reports of migration?
MR. O'CONNOR: Objection. Leading.
THE COURT: Sustained.
BY MR. ROGERS:
Q. Can you describe this percentage to the jury, please?
A. Yes. 0.16 means that there would be one out of every 1,000 patients could be expected to have that event.
MR. ROGERS: All right. We can take that down.
And can we pull up Exhibit 5539, please.
BY MR. ROGERS:
Q. And what is this document?
A. This is a copy of the failure investigation report that I

signed off on.
Q. All right. So you were one of the signatories of this document?
A. Yes.
Q. And so when you were at C.R. Bard, you were familiar with this document?
A. Yes.
Q. And did you participate in the preparation of this document?
A. Yes.
Q. And was this document maintained in the ordinary course of business at C.R. Bard?
A. Yes.
MR. ROGERS: Your Honor, I move this into evidence.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit No. 5539 admitted into evidence.)
MR. ROGERS: May we display it?
THE COURT: Yes.
BY MR. ROGERS:
Q. All right. Can you explain to the jury what a failure investigation report is?
A. Yes. When we received the reports of caudal migration, when it exceeded those low thresholds that we had, we conducted an investigation. And as part of that investigation, we

conducted an extensive cross-functional review of all of the information that we had. And then this is a summary report of all of that investigation outcome.

MR. ROGERS: All right. Can we go to page 5, please. And can we pull out the part at the bottom, 6.0.

BY MR. ROGERS:

Q. And can you tell us what this is?

A. Yes. This is a summary of the -- what we assessed as potential root causes of the failure. And it's talking about the tool that we used, which was a fishbone diagram, and also the expert opinion from Dr. Anthony Venbrux, who also reviewed the information related to the report.

Q. And what type of doctor is Dr. Venbrux?

A. Dr. Venbrux is an interventional radiologist. I believe he's an interventional radiologist. And he practiced at the -- at a hospital in -- near Washington, DC.

Q. And does he work for C.R. Bard?

A. No.

Q. And so how did he become involved in this?

A. He was a well-known physician that was -- that used vena cava filters. He was regarded in the medical society as a key opinion leader, and we contacted him and got a consulting agreement with him to ask him to provide input and review of our failure investigation.

MR. ROGERS: All right. Can we go to page 7 of the

document, please.

And can you try to make that just a little bit bigger, please?

BY MR. ROGERS:

Q. And what did Bard ask Dr. Venbrux to do?

A. We asked Dr. Venbrux to review all of the complaints related to caudal migration. And that was something that was really important to me, and ask him to actually come to -- here to Arizona and sat down with him and reviewed the imaging and the cases from each one of these events.

Q. Were you present in the room when Dr. Venbrux was doing his review?

A. Yes, I was.

Q. And so what was the purpose of asking him to look at these complaints?

A. I mean, we wanted to take them very seriously. And based upon the reports, they appeared to be asymptomatic, but we really wanted to get his input to see if there was anything that we were missing and thought that from a physician's perspective he might be able to identify something that would be relevant for our investigation to better understand these events.

Q. And what actions did Bard take based on Dr. Venbrux's review of the imaging?

A. Based on his review of the imaging, he felt that most of

these caudal migrations, again, were asymptomatic and that they were not likely to result in clinical sequelae to the patients.

MR. ROGERS: All right. You can take that down.

THE COURT: All right. We're going to break at this point.

Before you stand up, though, ladies and gentlemen, Traci handed me a note as you came in earlier indicating that you had questioned whether we're going to finish this week.

The answer is yes, we expect to finish this week. We're on schedule. I'll talk to the lawyers to get a more precise timing for you, but we anticipate that this case will be done by Friday.

I know Juror No. 9 particularly has plans next week, so we're planning to get it done. Don't be concerned about that. But I'll talk with the lawyers so we can give you something even more precise later today.

And we'll excuse the jury at this time.

(Jury not present.)

THE COURT: You can step down.

All right. Counsel, I'll give you your time summaries. But let me just -- just so you have it, I'll read you the note that Traci handed me when the jury came back in from the break.

It says: Jurors expressed concerns with finishing this week. Juror No. 9 has conflict next week. She will --

THE COURTROOM DEPUTY: Give me a note. Tell me what it is.

THE COURT: She will be giving me -- I see -- she will be giving me a note to explain at break.

So that's why I said what I did to them.

Let me get your time quickly, and then we can just talk about what more I ought to tell them.

All right, counsel. As of lunch today, plaintiffs have used 30 hours and 18 minutes; defendants, 18 hours and 41 minutes.

As I have timed this out for the week, if you all use all of your time but you reserve an hour for any potential punitives case, then we can get the case to the jury by the close of business on Wednesday. Maybe not with instructions. Instructions might be needed Thursday morning. But that would give them Thursday to -- and Friday to deliberate, plus time in there for punitive damages.

I don't know if you're going to use all of your time or not, defense counsel. Do you know?

MR. ROGERS: Well, Your Honor, we do want to reserve time, obviously, for closing. I mean, I think we'll be close if we don't. So it's kind of hard to say. We've got six more witnesses, I believe, and video that we're also going to want to show, so I would think it's going to track probably pretty close to the amount of time that's been allotted.

THE COURT: All right. Then my plan will be to tell the jury we expect to get the case to them at the end of the day Wednesday or the start of the day Thursday, so they know they're going to have a couple of days for deliberation.

All right. We'll see you --

MR. ROGERS: Your Honor, may I raise an affirmative point on that?

THE COURT: Pardon?

MR. ROGERS: May I raise an affirmative point, a question, really, about the time?

THE COURT: Yes.

MR. ROGERS: You know, in the prior two trials, plaintiffs have wound up receiving additional time, and I believe both parties got additional time. And if that is going to happen, I think it would be very helpful and fair if we knew that now so that we can budget the time that we have.

So I'm just raising the issue, and particularly how it also dovetails in with the Court's schedule and plan to get this to the jury.

MR. LOPEZ: Well, you know, this is another thing that's been haunting -- haunts us again in this trial, and that is the best-laid plans.

We believe that we had organized our whole case in chief so that we would have more time than we currently have left. There's no doubt about that. And I think what's been

more detrimental probably to us than to the defense is that -- and I'm not suggesting the Court shouldn't do it this way. I think it becomes too difficult on who gets charged for the sidebars.

But we've had probably two and a half hours, maybe more, of sidebars and every -- I mean, half of that time against our time, I mean, historically these two trials, the defense has five, six hours they don't use.

THE COURT: I have not been charging them half and half.

MR. LOPEZ: Okay.

THE COURT: What I do is if somebody calls for a sidebar, comes up, makes an argument, and they are unsuccessful and it clearly wasn't well taken, I give them all the time. If they come up and they make an argument and they're right and they prevail, I typically give the time to the other side.

If we're going back and forth at length, as we did this morning, I gave you a total of five minutes of sidebar time this morning. So just so you know, I'm not just cutting it in half. I'm trying to allocate it based on the merit of who's using the time.

MR. LOPEZ: But we're at a point now where those minutes are pretty precious to us.

THE COURT: I understand.

MR. LOPEZ: And, you know, we absolutely believe we

will be able to finish this case within the 33 hours you allotted, but except for maybe our time to argue the case. I mean, we -- there's a lot of evidence coming in over the next two days and, you know, we did in the Jones case. We just fast-tracked our way through cross-examination.

All's I can tell you is we're doing the best we can, Your Honor. We've had a lot of sidebar issues that have come up because of, you know, I think everybody's struggling with kind of some of the legal issues we've been involved in here.

And again, I know counsel says they plan on using all their time, but maybe they will, maybe they won't. But --

THE COURT: Well, let me look at something here.

(The Court and the courtroom deputy confer.)

THE COURT: So by my math, there are a total of 14 hours and 1 minute left in the allotted time. In other words, if we take the 63 hours, we've used all but 14 hours and 1 minute.

If we assume -- the punitive cases haven't been very long. It seems to me 45 minutes per side is enough for the punitive cases, because it's really just the financials and argument.

So if we assume each side reserved 45 minutes, that would mean that we would use 12 hours and 30 minutes of additional time before it goes to the jury.

We've got, today, another -- if we go till 4:30,

another 3 hours and 15 minutes. Tomorrow we'll have 5 and a half hours, and Wednesday we'll have 5 and a half hours. That means we've got 14 hours and 15 minutes of trial time between now and the close of trial.

And if we're reserving that time for punitives, we've got 12 hours and 30 minutes of time for you all to use. So that tells me that we've got about an hour and 45 minutes of wiggle room to get to the end of Wednesday and still reserve 45 minutes per side. That includes closing arguments, if I instruct the jury on Thursday morning.

And I'm willing, because we're there, to take that -- got to make sure my math is right -- yeah, that hour and 45 minutes and divide it among you now so you know you've got the additional time now. So that would be giving each side 50 more minutes in your case for whatever you choose to do between now and when it goes to the jury, and that would leave 45 minutes per side for punitives.

Is that helpful if we do that?

MR. LOPEZ: Did you say that included the 45?

THE COURT: No, no. We'd give you 50 minutes more.

MR. LOPEZ: Right.

THE COURT: So we'll just give each side 50 minutes more. You can reserve as much as you choose to for punitives. My point is if each side reserves 45 minutes for punitives, giving you each 50 minutes more won't push us past Wednesday

evening on finishing the evidence and argument in the case.

MR. LOPEZ: Yeah. Those are precious minutes for us, Your Honor.

THE COURT: Okay. Well, and in fairness to the defendants, so you know you've got it, let's do that then.

What we will say is each side gets 50 more minutes, so that means -- well, we'll just leave it there. I'll give you totals at the end of the day and you can figure it out.

That means plaintiff has 33 hours and 50 minutes, defense has 30 hours and 50 minutes.

And I'll tell the jury when they come in that we expect to complete evidence and argument by the close of business -- well, let's see. I've got to instruct before closings.

Well, I still think we can -- I still think we can do it. I still think we can get it to the jury by the close of Wednesday. I don't want to split your argument so somebody has to wait overnight to finish their argument or one side argues before they go home.

But the instructions aren't that long under Wisconsin law, so I'm thinking I can do it in 15 or 20 minutes and we can -- I'll tell the jury we expect to get the case to them by 4:30 on Wednesday so they'll come back Thursday to deliberate, and that will be with each of you having 50 more minutes.

Anybody see my math mistaken or any issue with that?

MR. ROGERS: I don't know that anybody's capable of discerning the mistake. But I think it sounded good.

But I did want to follow up on that one point, though, that Your Honor --

THE COURT: I've got somebody waiting on the phone so --

MR. ROGERS: Sure. Go ahead.

THE COURT: Do we need to talk about it right now?

MR. ROGERS: No, sir. It can wait.

THE COURT: Okay. But everybody's getting 50 more minutes. That's the decision as of now.

Okay. Thanks.

MR. LOPEZ: Thank you, Your Honor.

(Proceedings recessed at 12:11 p.m.)

C E R T I F I C A T E

I, JENNIFER A. PANCRATZ, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 1st day of October, 2018.

s/Jennifer A. Pancratz
Jennifer A. Pancratz, RMR, CRR, FCRR, CRC